95TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 95-1004
Part 3

CLINICAL LABORATORY IMPROVEMENT ACT OF 1978

REPORT

BY THE

COMMITTEE ON WAYS AND MEANS

INCLUDING THE CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

[To accompany H.R. 10909]

JULY 12, 1978.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE
29-006 WASHINGTON : 1978

COMMITTEE ON WAYS AND MEANS

AL ULLMAN, Oregon, *Chairman*

JAMES A. BURKE, Massachusetts
DAN ROSTENKOWSKI, Illinois
CHARLES A. VANIK, Ohio
OMAR BURLESON, Texas
JAMES C. CORMAN, California
SAM M. GIBBONS, Florida
JOE D. WAGGONNER, JR., Louisiana
OTIS G. PIKE, New York
J. J. PICKLE, Texas
CHARLES B. RANGEL, New York
WILLIAM R. COTTER, Connecticut
FORTNEY H. (PETE) STARK, California
JAMES R. JONES, Oklahoma
ANDY JACOBS, JR., Indiana
ABNER J. MIKVA, Illinois
MARTHA KEYS, Kansas
JOSEPH L. FISHER, Virginia
HAROLD FORD, Tennessee
KEN HOLLAND, South Carolina
WILLIAM M. BRODHEAD, Michigan
ED JENKINS, Georgia
RICHARD A. GEPHARDT, Missouri
JIM GUY TUCKER, Arkansas
RAYMOND F. LEDERER, Pennsylvania

BARBER B. CONABLE, JR., New York
JOHN J. DUNCAN, Tennessee
BILL ARCHER, Texas
GUY VANDER JAGT, Michigan
WILLIAM A. STEIGER, Wisconsin
PHILIP M. CRANE, Illinois
BILL FRENZEL, Minnesota
JAMES G. MARTIN, North Carolina
L. A. (SKIP) BAFALIS, Florida
RICHARD T. SCHULZE, Pennsylvania
BILL GRADISON, Ohio
JOHN H. ROUSSELOT, California

JOHN M. MARTIN, JR., *Chief Counsel*
J. P. BAKER, *Assistant Chief Counsel*
JOHN K. MEAGHER, *Minority Counsel*

CONTENTS

	Page.
I. Purpose and background of the bill	7
II. Summary of the bill	8
III. General statement	8
A. Title I—Public Health Service Act amendments	8
B. Title II—Social Security Act amendments	12
Amendments to title XIX (medicaid) of the Social Security Act	12
Billing requirements for clinical laboratory tests	12
Applicability of JCAH hospital laboratory standards	14
Percentage arrangements for hospital-based physicians	14
Conforming amendments to title XVIII	15
IV. Cost of carrying out the bill and effect on the revenue	16
V. Other matters to be discussed under the House rules	18
VI. Section-by-section analysis	19
VII. Changes in existing law made by the bill, as reported	37

95TH CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 95–
2d Session } { 1004, Part 3

CLINICAL LABORATORY IMPROVEMENT ACT OF 1978

JULY 12, 1978.—Ordered to be printed

Mr. ULLMAN, from the Committee on Ways and Means, submitted the following

REPORT

[To accompany H.R. 10909 which on February 9, 1978, was referred jointly to the Committee on Interstate and Foreign Commerce and the Committee on Ways and Means]

[Including Cost Estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 10909) to amend the Public Health Service Act to revise and strengthen the program under that Act for national standards for and licensing of clinical laboratories, to amend the Social Security Act to require laboratories providing services financed under titles XVIII and XIX of such Act to meet the requirements of such program, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments (stated in terms of the page and line numbers of the introduced bill) are as follows:

Page 17, lines 1 and 2, strike out "kickback or bribe in the form of money or any other thing of value" and insert in lieu thereof the following:

> remuneration (including any kickback, bribe, finder's fee, or rebate, but excluding any discount or other reduction in price and excluding any amount paid by an employer for employment in the provision of the services) directly or indirectly, overtly or covertly, in cash or in kind

Page 39, strike out line 6 and all that follows through page 40, line 17, and insert in lieu thereof the following (and amend the table of contents accordingly):

AMENDMENT TO TITLE XI OF THE SOCIAL SECURITY ACT

SEC. 201. Section 1124(a)(1) of the Social Security Act is amended by inserting before the period at the end of the

following: ", and in the case of a disclosing entity which is an independent clinical laboratory, furnish such information and access to its records as the Secretary may require to determine whether and in what amounts the laboratory has charged a physician for laboratory services performed by the laboratory".

Page 40, strike out line 18 and all that follows through page 46, line 17, and insert in lieu thereof the following:

AMENDMENTS TO TITLE XVIII OF THE SOCIAL SECURITY ACT

SEC. 202. (a) (1) Section 1842 of the Social Security Act is amended by inserting at the end the following new subsection:

"(h) If a physician's bill or request for payment for a physician's services includes a charge to a patient for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows:

"(1) If the bill or request for payment indicates that the physician who submitted the bill or for whose services the request for payment was made personally performed or supervised the performance of the test or that another physician with whom that physician shares his practice personally performed or supervised the test, the payment shall be the reasonable charge for the test (less the applicable deductible and coinsurance amounts).

"(2) If the bill or request for payment indicates that the test was performed by a laboratory, identifies the laboratory, and indicates the amount the laboratory charged the physician who submitted the bill or for whose services the request for payment was made, payment for the test shall be the lower of—

"(A) the laboratory's reasonable charge to individuals enrolled under this part for the test, or

"(B) the amount the laboratory charged the physician for the test,

plus a nominal fee (where the physician bills for such a service) to cover the physician's costs in collecting and handling the sample on which the test was performed (less the applicable deductible and coinsurance amounts).

"(3) If the bill or request for payment (A) does not indicate who performed the test, or (B) indicates that the test was performed by a laboratory but does not identify the laboratory or include the amount charged by the laboratory, payment shall be the lowest charge at which the carrier estimates the test could have been secured by a physician from a laboratory serving the locality (less the applicable deductible and coinsurance amounts).".

(2) The amendments made by paragraph (1) shall apply to bills submitted and requests for payment made on or after such date (not later than July 1, 1979) as the Secretary of Health, Education, and Welfare (hereinafter in this title referred to as the "Secretary") prescribes by a notice published in the Federal Register.

(b)(1)(A) The second sentence of section 1861(s) of the Social Security Act is amended to read as follows: "No diagnostic tests performed in any laboratory shall be included in paragraph (3) unless the laboratory meets applicable Federal or State licensing requirements under part H of title III of the Public Health Service Act, or, if those requirements are not applicable, meets such conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.".

(B)(i) Paragraphs (12) and (13) of section 1861(s) of such Act are redesignated as paragraphs (10) and (11), respectively.

(ii) The first sentence of section 1864(a) of such Act is amended by striking out "the requirements of paragraphs (10) and (11) of section 1861(s)" and inserting in lieu thereof "the requirements of section 1861(e)(9), section 1861(j)(15), or the second sentence of section 1861(s)".

(2)(A) Section 1861(e) of such Act is amended—

(i) by striking out "and" after the semicolon at the end of paragraph (8);

(ii) by redesignating paragraph (9) as paragraph (10); and

(iii) by inserting after paragraph (8) the following new paragraph:

"(9) meets applicable Federal or State licensing requirements under part H of title III of the Public Health Service Act with respect to any laboratory which is a part of the institution; and".

(B) Section 1861(j)(15) of such Act is amended by inserting after "physical facilities thereof" the following: "(including applicable Federal or State licensing requirements under part H of title III of the Public Health Service Act with respect to any laboratory which is a part of the institution)".

(C)(i) Subparagraphs (C) and (D) of section 1814(a)(2) of such Act are each amended by striking out "and (9)" and inserting in lieu thereof "and (10)".

(ii) Subsections (f)(2) and (g)(2) of section 1861 of such Act are each amended by striking out "(3) through (9)" and inserting in lieu thereof "(3) through (10)".

(iii) Section 1865(a)(4) of such Act is amended by striking out "paragraph (9)" and inserting in lieu thereof "paragraph (10)".

(3) The first sentence of section 1864(a) of such Act is amended by inserting before the period at the end thereof the following: "; except that the Secretary may not make

an agreement with a State under this sentence for the purpose of determining whether a laboratory meets the requirements of section 1861(e)(9), section 1861(j)(15), or the second sentence of section 1861(s) (or include provision for such purpose in any such agreement) unless either the State has primary enforcement responsibility for the regulation of clinical laboratories as determined under part H of title III of the Public Health Service Act, or the State provides assurances satisfactory to the Secretary that it will implement procedures for the enforcement of such requirements".

(c)(1) The first sentence of section 1865(a) of the Social Security Act is amended—

(A) by striking out "and" at the end of paragraph (3);

(B) by redesignating paragraph (4) as paragraph (5); and

(C) by inserting after paragraph (3) the following new paragraph:

"(4) paragraph (9) thereof, and".

(2) The second sentence of such section is amended—

(A) by inserting before "or imposes" the second time it appears the following: ", imposes standards with respect to laboratories which the Secretary (and the applicable State agency designated in accordance with section 374(a)(6) of the Public Health Service Act, in the case of any laboratory in a State which has primary enforcement responsibility under part H of title III of such Act) determines are at least equivalent to the national standards for clinical laboratories in effect under section 371 of such Act,";

(B) by inserting ", section 1861(e)(9)," after "section 1861(e)(6)"; and

(C) by striking out "paragraph (4)" and inserting in lieu thereof "paragraph (5)" each place it appears.

(3) The third sentence of such section is amended by inserting after "the Secretary" the following: "(and the applicable State agency designated in accordance with section 374(a)(6) of the Public Health Service Act, to the extent that licensing requirements for laboratories under part H of title III of such Act, as specified in section 1861(e)(9) or 1861(j)(15) of this Act, are involved, if the institution or agency is located in a State which has primary enforcement responsibility under part H of title III of such Act)".

(d)(1) Section 1833 of the Social Security Act is amended—

(A) by striking out "subsection (g)" in subsection (a)(1)(D) and inserting in lieu thereof "subsection (h)"; and

(B) by redesignating as subsection (h) the subsection (g) that begins "With respect to diagnostic tests" and was added by section 279(b) of the Social Security Amendments of 1972.

(2) Sections 1833(g), 1832(a)(2)(C), and 1833(a)(2)(C) of such Act are each amended by striking out "next to last sentence of section 1861(p)" and inserting in lieu thereof "the second sentence of section 1861(p)".

(3) Section 1837(g)(1) of such Act is amended (A) by striking out "section 226(a)(2)(B)" and inserting in lieu thereof "section 226(b)" and (B) by striking out "section 1839(e)" and inserting in lieu thereof "section 1839(f)".

(4) Section 1866(a)(1)(B) of such Act is amended by inserting "of section 1862(a)" after "paragraphs (1) or (9)" and section 1870(c) of such Act is amended by striking out "section 1862" and inserting in lieu thereof "section 1862(a)".

Page 50, strike out line 4 and all that follows through page 51, line 3, and insert in lieu thereof the following (and amend the table of contents accordingly):

PERCENTAGE ARRANGEMENTS OF HOSPITAL-BASED PHYSICIANS

SEC. 204. (a) Title XI of the Social Security Act is amended by inserting after section 1126 the following new section:

"PERCENTAGE ARRANGEMENTS OF HOSPITAL-BASED PHYSICIANS

"SEC. 1127. (a) Notwithstanding any other provision of this Act, if a physician (or physicians) performs a professional service in a hospital and the hospital's payment to the physician (or physcians) for the service is based on a percentage of the hospital's charges (or of hospital amounts otherwise calculated) for the service, no part of such payment shall be considered reasonable for the purpose of reimbursement under title V, XVIII, or XIX, to the extent that the part exceeds the sum of—

"(1) the compensation which would reasonably have been paid by the hospital to the physician (or physicians) performing the service (taking into consideration the local and individual circumstances under which the services are provided in that hospital) and additional costs that would have been incurred by the hospital, if the service had been performed by the physician (or physicians) in an employment relationship with the hospital, and

"(2) the cost of such other reasonable expenses (including a reasonable allowance for traveltime and other reasonable types of expense related to differences in acceptable methods of organizing the provision of the service) incurred by the physician (or physicians) in performing the service, as the Secretary determines to be appropriate.

"(b) Notwithstanding any other provision of this Act, if a physician (or physicians) furnishes professional services in a hospital to patients of the hospital and if these services

are furnished in the hospital under a rental or lease arrangement under which arrangement the hospital is paid an amount that is based (directly or indirectly) on a percentage, fraction, or proportion of the charges made for the services furnished, the amount that shall be treated as a reduction from the hospital's costs otherwise allowable under titles V, XVIII, and XIX, with respect to its receipt of payments under the arrangement, shall be the greater of—

"(1) the amount paid to the hospital under the arrangement with respect to the services furnished, or

"(2) the amount by which (A) the charges made by the physician (or physicians) for the furnishing of the services, exceeds (B) the amount of the costs which would have been incurred for the furnishing of the services if they were furnished directly by the hospital through individuals who were all employed on a reasonable compensation basis by the hospital, rather than under such arrangements."

(b)(1) Except as provided in paragraph (2), section 1127 (a) of the Social Security Act (as added by subsection (a)) shall apply to payments for professional services performed by physicians on and after the first day of the first calendar quarter that begins more than 60 days after the date of enactment of this Act.

(2) If professional services are performed by a physician (or physicians) under a contract with a hospital entered into on or before June 1, 1978, section 1127(a) of the Social Security Act shall only apply to payments for professional services performed under the contract after (A) the date of termination of the contract, or (B) May 31, 1979, whichever occurs earlier.

(c)(1) Except as provided in paragraph (2), section 1127 (b) of the Social Security Act (as added by subsection(a)) shall apply to payments received by hospitals with respect to those professional services which are performed in a hospital (under a rental or lease arrangement) on and after the first day of the first calendar quarter that begins more than 60 days after the date of enactment of this Act.

(2) If a hospital receives payments under a rental or lease arrangement entered into before June 1, 1978, section 1127 (b) of the Social Security Act shall only apply to payments received with respect to professional services performed after (A) the date of termination of the arrangement, or (B) May 31, 1979, whichever occurs earlier.

Page 51, strike out lines 4 through 22 and insert in lieu thereof the following:

REPORT ON BILLING FOR LABORATORY SERVICES

SEC. 205. Not later than twenty-four months after the effective date of the amendments made by section 202(a), the Secretary shall report to the Congress (1) the proportion of bills and requests for payment submitted (during the eight-

een-month period beginning on such effective date) under title XVIII of the Social Security Act for laboratory tests which did not identify who performed the tests, (2) the proportion of bills and requests for payment submitted during such period for laboratory tests with respect to which the amount paid under such title was less than the amount that would otherwise have been payable in the absence of section 1842(h) of such Act, (3) with respect to requests for payment described in clause (2) which were submitted by patients, the average additional cost per laboratory test to patients resulting from reductions in payment that would otherwise have been made for such tests in the absence of such section 1842(h), and (4) with respect to bills described in clause (2) which were submitted by physicians, the average reduction in payment per laboratory test to physicians resulting from the application of such section 1842(h).

I. Purpose and Background of the Bill

Your committee is concerned about the lack of coordination and consistency in the application of quality assurance standards for clinical laboratories. Currently, different statutory authorities apply to different laboratories depending upon their location. Under medicare, for example, standards applied to laboratories located outside hospitals differ somewhat from those applied to laboratories located within hospitals; and among those laboratories located within hospitals some are subject to standards promulgated by the Secretary of Health, Education and Welfare while others must meet standards applied by the Joint Commission on Accreditation of Hospitals. In addition, clinical laboratories engaged in interstate commerce are subject to standards developed and applied under authority provided in the Public Health Service Act. It is clear that this situation has given rise to a significant degree of administrative duplication as well as variations in the applicable standards.

Your committee is concerned also about certain types of financial arrangements between physicians and hospitals (including arrangements to provide pathology services) and cestain billing and pricing practices with respect to clinical laboratory services which have contributed to abuse, waste and overpayments in the medicare and medicaid programs. Information furnished to your committee by the General Accounting Office indicates that such practices as excessive markups on bills for laboratory services are pervasive and costly to the program. Your committee is convinced that there is a compelling need to protect both the medicare program and its beneficiaries against the continued use of such practices.

A bill to amend the Social Security and Public Health Service Acts to revise and coordinate existing programs for the regulation of clinical laboratories (H.R. 6221) was introduced on April 6, 1977, and jointly referred to the Committees on Ways and Means and Interstate and Foreign Commerce. The Commerce Committee's Subcommittee on Health and the Environment reported, and reintroduced as a clean bill, H.R. 10909, on February 9, 1978. Subsequently,

H.R. 10909 was considered by the full Commerce Committee and ordered reported with amendments on March 15, 1978.

On May 9, 1978, a public hearing on H.R. 10909 was held by your committee's Subcommittee on Health. The subcommittee considered this legislation in executive session on June 6, 1978, reporting the bill with amendments to the full committee, and the full Committee on Ways and Means considered H.R. 10909 and ordered it reported as amended on July 11, 1978.

Comparable legislation, S. 705, passed the Senate on July 28, 1977.

II. Summary of the Bill

As reported, H.R. 10909 would modify present law to provide for the implementation of a uniform Federal licensure system for clinical laboratories based upon compliance with quality standards to be promulgated by the Secretary of Health, Education and Welfare. Since one of the major objectives of the bill is to encourage states to assume responsibility for the inspection and licensure of clinical laboratories, the Secretary is authorized to delegate his licensure authority to states implementing programs equivalent to the Federal program.

Other elements of the system include: the exemption of physicians' office laboratories where the physicians perform the tests themselves for their own patients; waiver of supervisory and technical personnel standards for a period of time for clinical laboratories in rural areas; provision for penalties for kickbacks and other fraudulent practices in connection with clinical laboratory services; authority for the Secretary to utilize qualified public and nonprofit private entities to conduct surveys of clinical laboratories and to administer laboratory proficiency tests; and provision for the Secretary to conduct studies concerning the qualifications of laboratory personnel, proficiency testing methodologies, and the effect of this legislation on the cost and quality of clinical laboratory services.

The bill would also modify the reimbursement provisions of present law with respect to (1) arrangements between hospitals and physicians under which payments to either party are based on a percentage of the total amount billed for the services performed, and (2) charges for clinical laboratory services included in a physician's bill.

Although the Committee on Ways and Means limited its actual amendments to the bill to those provisions of it relating to the medicare program, for purposes of the committee's deliberations and this report it has been assumed that the amendments adopted by the Committee on Interstate and Foreign Commerce constitute an integral part of the bill.

III. General Statement

Explanation, Justification, and Comparison with Present Law

A. Title I, sections 101–105—Public Health Service Act amendments

The bill would modify present law to provide for the implementation of a uniform Federal licensure system for clinical laboratories based upon compliance with quality standards to be promulgated by the Secretary of Health, Education, and Welfare.

Under present law, there is in existence a limited Federal licensure system for clinical laboratories directly engaged in interstate commerce, and a clinical laboratory certification system under medicare and medicaid applicable to nonhospital clinical laboratories. (Under medicare, a hospital laboratory is surveyed and certified as part of the hospital. Moreover, hospital laboratories may be subject to different standards; those in hospitals accredited by the Joint Commission on Accreditation of Hospitals (JCAH) must meet JCAH standards, and those in nonaccredited hospitals must meet standards established by the medicare program.) H.R. 10909 would absorb these several systems into a single, uniform clinical laboratory licensure program. The implementation of this program would eliminate the overlapping and duplication that now occurs under present law in applying clinical laboratory standards.

The licensure program that would be established under these provisions of the bill would include the following elements:

1. *National standards.*—The Secretary would be required to establish national standards for clinical laboratories to assure accurate testing, including standards relating to the maintenance of quality controls, laboratory equipment and procedures, record-keeping, periodic on-site proficiency testing (and the optional use of blind proficiency testing), and qualifications for laboratory personnel. Such standards are to be promulgated by the Secretary within one year after enactment.

2. *Application of national standards.*—The standards would be effective upon promulgation and apply to all clinical laboratories with the following exceptions:

(*a*) The standards would not be applicable to intrastate laboratories (which include most hospital-based laboratories) until two years after their promulgation;

(*b*) Requirements relating to supervisory and technical personnel qualifications would be delayed for four years for a clinical laboratory located in a rural area where qualified personnel are not available, the laboratory performs services only for hospitals and practitioners located in the rural area, and the laboratory provides assurances that it will make efforts to train or recruit individuals who will meet the requirements;

(*c*) The standards would not be applicable to: (i) a laboratory in the office of a physician, dentist or podiatrist where the only tests done are performed by the practitioner for his own patients; (ii) a laboratory located in the office of a group of not more than five such practitioners in which testing is done only for the group's patients, provided the laboratory agrees to participate in a study of practitioners' office laboratories; and (iii) a laboratory in which the only tests performed are for biomedical or behavioral research;

(*d*) Highly specialized laboratories engaged exclusively in the assessment of cardiac or pulmonary function would be exempt from the standards for two years from the date of enactment; however, at the end of such period, the Secretary is required to issue regulations establishing appropriate national standards for such laboratories;

(*e*) Federal clinical laboratories would be subject to the standards unless: (i) they are under the jurisdiction of the Armed Forces or the Veterans' Administration, or (ii) the agency with jurisdiction has equally stringent standards.

3. *Licensure.*—The Secretary would be required to establish a system of licensure under which a license is to be issued upon application where the laboratory is in compliance with the standards, files a schedule of fees charged for services and discloses any contractual agreements between the applicant and physicians regarding laboratory services. Revocation or suspension of a license for failure to comply with the licensure requirements or for fraudulent or improper activities in connection with the solicitation, performance or payment for laboratory services (including the payment of founder's fees and kickbacks) is authorized. Provision is made for judicial review of such revocation actions. The Secretary is authorized to inspect laboratories for the purpose of establishing compliance with licensure requirements.

4. *Delegation of primary enforcement responsibility to a State.*—A State may assume primary enforcement responsibility for the regulation of laboratories located within its jurisdiction if: (a) it has adopted standards no less stringent than the national standards; (b) has established an enforcement mechanism; (c) permits exemptions from its standards under conditions not less stringent than Federal conditions; (d) has procedures for controlling health hazards; and (e) has designated a single State agency for enforcement of the standards and administration of the licensure system.

5. *Agreements.*—The Secretary (and a State with primary enforcement responsibility) would be authorized to enter into agreements with qualified public or nonprofit private entities to conduct inspections of clinical laboratories and/or administer laboratory proficiency tests.

6. *Employee protection.*—An employer is prohibited from discharging or discriminating against an employee because the employee commenced or testified in a Federal or State proceeding relating to violations of this legislation, and the Secretary of Labor is authorized to investigate such complaints and to order reinstatement in appropriate instances, subject to judicial review.

7. *Studies.*—The Secretary of HEW is to conduct studies relating to standards for laboratory personnel and services, proficiency testing methodologies, the scope and quality of laboratory testing in various types of practitioners' offices, and the effect of this legislation on the quality and cost of laboratory services.

8. *Grants.*—The bill authorizes the Secretary to make grants to States with primary enforcement responsibility to assist them in meeting the costs of administration.

Your committee has concluded, based on its consideration of this title of the bill, that some additional clarification of the intent of certain provisions is necessary. Thus, with respect to the provision relating to proficiency testing, the committee notes that widespread application of certain types of proficiency testing methodologies, particularly blind proficiency testing, may involve significant logistical problems. In light of this consideration, the committee believes it would be appro-

priate to apply blind proficiency testing on a selective basis where, for example, the Secretary already has evidence from other sources that the laboratory's practices are questionable or fraudulent. It is expected, therefore, that the Secretary would use any blind proficiency testing programs developed under this legislation on such a selective basis. It is also expected that the Secretary will continue to utilize, wherever and to the extent he finds it appropriate, those proficiency testing programs now being conducted in conjunction with the administration of the present interstate laboratory licensure program by both the Federal goverment and recognized private professional organizations.

Your committee also notes that the provision for the revocation of a laboratory's license in the event an individual associated with the laboratory is convicted of a fraudulent act under sections 1877(b) or 1909(b) of the Social Security Act (the "anti-fraud" provisions of present medicare and medicaid law), or under section 375 of the Public Health Service Act as added by this bill, may not delineate with sufficient precision the intended scope of this provision. It is necessary, therefore, to emphasize the intent that such revocation action would be taken only where the individual so convicted is an individual with an ownership or control interest (as defined in section 1124(a)(3) of the Social Security Act) in the laboratory.

It is your committee's understanding that the intent with respect to a laboratory which has separate physical locations or collection stations but which has central control, management and supervision of the activities of all these separate locations is that one license would cover such a group of centrally managed facilities in one geographic area.

Finally, your committee wishes to take note of what might appear on the surface to be a disparity in the timing of the application of national standards to specialized laboratories (particularly cardiac and pulmonary function laboratories) and all other intrastate laboratories. Under the bill, the national standards are not applicable to intrastate clinical laboratories until two years following the promulgation of the standards. (The Secretary must promulgate such standards within one year after enactment.) The bill also provides that within two years after enactment the Secretary is to promulgate regulations to make national standards applicable to specialized laboratories. It is clear that the intent of these provisions is to (1) permit sufficient time for the Secretary, in the case of cardiac and pulmonary function laboratories, to consult with hospital administrators and others knowledgeable in medical laboratory procedures and to consider any special conditions that need to be taken into account before prescribing standards for such laboratories; and (2) provide sufficient time for all laboratories, following promulgation of the standards, to take the necessary steps to come into compliance with the standards. Thus, the committee expects that the applicable national standards for cardiac and pulmonary function laboratories will be made effective at the same time as standards are made effective for intrastate clinical laboratories. It is also expected that standards under present law for such laboratories will continue to be applied until the new standards become effective.

Your committee also wishes to take note of certain differences expressed by committee members with respect to other provisions of this title. Thus, the committee has some concern about the application of the national standards to laboratories engaged solely in the assessment of an individual's insurability or eligibility for insurance benefits. The committee believes it would be preferable to continue the exemption of insurance examination and testing procedures now provided for under the clinical laboratory legislation enacted in 1967.

Your committee also notes that while the bill provides for a phased approach to the implementation of standards relating to supervisory and technical personnel qualifications for rural laboratories, the bill provides no authority, once the last phase has been implemented, to defer application of these standards to rural laboratories which experience problems in recruiting or retaining fully qualified people. It may be appropriate, therefore, to provide some discretionary authority for the Secretary to extend the personnel exemption for limited periods in those situations where a rural laboratory is experiencing a temporary shortage of qualified technical personnel.

B. Title II—Social Security Act amendments

Section 203—Amendments to Title XIX (Medicaid) of the Social Security Act

The bill would allow a State to purchase laboratory services for its medicaid population through competitive bidding arrangements for a 3-year experimental period. Under this provision, services may be purchased only from laboratories meeting standards and only if the laboratories charge the medicaid program at rates that do not exceed the lowest amount charged to others for similar tests. The bill would also make conforming changes in title XIX to provide that medicaid payments generally may be made only to clinical laboratories meeting applicable standards.

Your committee wishes to express its recommendation with respect to competitive bidding arrangements under medicaid that the specifications for each service bid upon include provision for the quality of the services to be furnished. The committee also notes some disagreement as to the most appropriate duration for assessing the effectiveness of competitive bidding arrangements.

Sections 202(a); 201; 205—Billing Requirements for Clinical Laboratory Tests

The bill provides that payments to physicians for laboratory services under medicare shall be determined as follows: (a) where the physician's bill indicates that the physician personally performed or supervised such services, payment would be the reasonable charge of the physician for such services; (b) where the bill indicates that the services were performed by a laboratory and specifies the amount the laboratory charged the physician, payment would be lower of: the laboratory's reasonable charge for such services or the amount the laboratory charged the physician, plus a nominal fee where the physician bills for such a service to cover the physician's costs in collecting and

handling the specimen; (c) where the bill does not indicate who performed the service or indicates the service was performed by a laboratory which is not identified, payment would be at the charge estimated to be the lowest charge at which the service could have been secured by a physician from a laboratory serving the locality.

Section 201 of the bill authorizes the Secretary to examine a laboratory's records to verify the amounts it charges physicians for services.

Section 205 of the bill requires the Secretary to study and report to the Congress (within 2 years after enactment) on the effect of the new billing provision with respect to physician billing practices and any changes in the average cost per laboratory service for the program and for beneficiaries.

Evidence accumulated by GAO, the Senate Subcommittee on Long-Term Care and HEW indicates that there are frequently substantial markups in bills submitted by physicians for laboratory services. In addition, such bills often do not identify the laboratory actually performing the tests which necessitates additional claims development by the medicare carrier to determine whether the laboratory is one that meets medicare's health and safety standards.

The bill addresses these problems by prescribing specific informational requirements for the completion of a physician's bill that includes laboratory services, and by adjusting payment in accordance with the provision of such information. Thus, the bill provides that when a physician includes an amount in his bill for laboratory services, he must indicate whether (i) he performed the service or (ii) the name of the laboratory performing the service and the amount the physician was charged by the laboratory. If the physician indicates he performed the service he would be reimbursed for his reasonable charge for that service.

If the physician indicates that the laboratory service was performed elsewhere and how much he was charged for that service, payment would be the lower of the laboratory's reasonable charge to medicare beneficiaries or the amount the laboratory actually charged him, plus a nominal fee for the collection and handling of the specimen. It is expected that the amount shown on a physician's bill as the amount charged by the laboratory for its service will reflect all reductions, such as volume discounts, to the extent that these are known to the physician or can be estimated by him based on past experience, as the time the bill is submitted. In order to verify (whenever necessary) the information supplied by the physician concerning these amounts, the bill authorizes program access to the laboratory's billing records.

Your committee believes that when payment is made for a laboratory service which a physician purchases from an outside source, it is reasonable to expect that the physician's charge to the patient for the purchased service will be in line with the laboratory's charge to the physician. The bill, therefore, provides that in such an instance program payment for the laboratory service be related to the laboratory's charge to the physician. The bill also provides for payment of a nominal fee for the physician's collection and handling of the specimen on which the outside laboratory test was performed in recognition of the fact that when a physician or paramedical in his employ extracts

a specimen from a patient he often incurs expenses in collecting, preparing, shipping and maintaining records concerning the specimen. It is expected, therefore, that the Secretary will take into account reasonable expenses of this kind in determining the amount of the nominal fee for this service.

Where the physician fails to provide the necessary information, the payment allowed for the laboratory service included in his bill would be the lowest charge at which such services could have been secured by a physician from a laboratory serving the locality. The intent is to provide a financial incentive for physicians to furnish the necessary information so that it can be readily determined that the laboratory is qualified and that there is no unreasonable markup included in the physician's charge for laboratory tests.

It is recognized that the financial consequences of the adjustments in reimbursement that would be made under this provision will be felt by the patient rather than the physician in those cases where the physician chooses not to take an assignment and to bill the patient directly for the amount reduced by the program. The issue is whether the medicare program should continue to pay excessive markups on laboratory tests because the failure of physicians to take assignment might result in some cases in increased out-of-pocket payments by beneficiaries. Your committee concluded that excessive program payments for markups on laboratory services could not be justified, but recognizing the potential consequences for beneficiaries requires the Secretary to report to the Congress within 2 years on the experience with this provision, particularly in regard to how frequently and in what amounts reductions in allowed payments affect beneficiaries.

Section 202(c)—Applicability of JCAH Hospital Laboratory Standards

The bill provides that if the Joint Commission on Accreditation of Hospitals imposes standards for hospital laboratories that are at least equivalent to the national standards, the Secretary (or the State, in the case of a State with primary enforcement responsibility) may deem a laboratory in a JCAH-accredited hospital to be in compliance with the national standards.

Under present law, a clinical laboratory located in a hospital accredited by the JCAH is deemed to meet medicare's health and safety standards. The Secretary is authorized, however, to set higher standards than those applied by JCAH and may, in such case, conduct inspections to verify compliance with those standards. The bill conforms to this present medicare policy by providing that JCAH accreditation will be acceptable as evidence of a hospital laboratory's compliance with national standards, if the Secretary determines that the JCAH's laboratory standards are at least equivalent to the national standards.

Section 204—Percentage Arrangements of Hospital-Based Physicians

The bill provides that costs incurred by a hospital (where the payment is based on a percentage of the hospital's total charges for the service) would not be reimbursed to the extent they exceed the sum of: (a) the reasonable compensation which would have been paid the

physician if he were in an employment relationship with the hospital, and (b) the cost of other reasonable expenses incurred by the physician. In addition, where a physician furnishes services to hospital patients under a lease arrangement and the amount paid to the hospital under the arrangement is based on a percentage of the physician's total charges, the hospital's allowable costs would be offset by the greater of: (1) the actual amount paid under the least (the amount which is ordinarily offset against costs), or (2) the difference between the total charges of the physician and what it would have cost the hospital to furnish the services through individuals employed by the hospital.

When rental and lease arrangements between hospitals and physicians, including pathologists, provide for payments to either party on the basis of a percentage of total charges for services furnished by the hospital department (for example, the hospital laboratory), the physician and/or hospital's compensation is directly related to the volume of services furnished. Although such arrangements often provide incentives to furnish excessive services, and thus increase the cost of laboratory and other services for the medicare and medicaid programs, there is no provision under present law to encourage more reasonable arrangements. The bill addresses this problem by providing that reimbursement for professional services to hospitals which have percentage arrangements with hospital-based physicians is to be related to the costs a hospital would have incurred in the absence of a percentage arrangement; i.e., if the services were furnished directly by the hospital through individuals in an employment relationship with the hospital. While the provision would not prohibit percentage arrangements as such, it would effectively discourage the development or continuation of those percentage arrangements that have given rise to excessive utilization and have generated unreasonable compensation.

In order to help facilitate conversion from percentage arrangements to other more reasonable contractual arrangements, the committee expects the Secretary to provide such assistance as is feasible to ease such conversions and to assure the prompt implementation of policies for reimbursement under such other types of arrangements.

Your committee believes that the unique situation of an isolated, rural hospital with respect to the provision of professional services warrants particular attention. The committee expects, therefore, that the Secretary will take fully into account in developing policies concerning the determination of potential hospital costs those special circumstances relating to the reasonable expenses incurred by a physician, such as traveling, the mode of transportation and other expenses arising from differences related to acceptable methods for organizing and providing services in such a hospital.

Section 202 (b) and (d)—Conforming Amendments to Title XVIII

The bill makes conforming changes in title XVIII to provide that payment for laboratory services under medicare may not be made unless the laboratory meets the applicable standards. These conforming amendments would assure the continuation of present medicare policy to require laboratory compliance with standards as a condition of medicare payment.

IV. Cost of Carrying Out the Bill and Effect on the Revenues

In compliance with subdivision (C) of clause 2(l)(3) of rule XI of the Rules of the House of Representatives, the statement relative to the estimated costs of carrying out the bill provided to your Committee by the Director of the Congressional Budget Office follows:

Congressional Budget Office,
U.S. Congress,
Washington, D.C. July 12, 1978.

Hon. Al Ullman,
Chairman, Committee on Ways and Means, U.S. House of Representatives, Washington, D.C.

Dear Mr. Chairman: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has prepared the attached cost estimate for H.R. 10909, the Clinical Laboratory Improvement Act of 1978.

Should the committee so desire, we would be pleased to provide further details on the attached cost estimate.

Sincerely,

Robert A. Levine,
(For Alice M. Rivlin,
Director).

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE

July 12, 1978.

1. Bill number: H.R. 10909.
2. Bill title: Clinical Laboratory Improvement Act of 1978.
3. Bill status: As amended by the Subcommittee on Health, the Committee on Ways and Means on June 12, 1978.
4. Bill purpose: To amend the Public Health Service and Social Security Acts in order to assure expanded and improved regulation of clinical laboratories and to reduce the present levels of reimbursement under Medicare and Medicaid for laboratory services.
5. Cost estimate:

[By fiscal years, in millions of dollars]

	1979	1980	1981	1982	1983
Inspection program: Authorization level/costs	3.00	3.00	3.00	3.00	3.00
Medicaid:					
Required budget authority	18.10	−46.00	−58.30	−5.60	−6.40
Outlays:					
Competitive bid laboratories	−16.00	−41.60	−53.10	0	0
Limitation on percentage arrangements for hospital-based physicians	−2.10	−4.70	−5.20	−5.60	−6.40
Total	−18.10	−46.30	−58.30	−5.60	−6.40
Medicare:					
Outlays:					
Exclusion of certain charges	−5.76	−6.34	−6.97	−7.87	−8.43
Limitation on percentage arrangements for hospital-based physicians	−6.20	−13.90	−15.70	−16.90	−19.00
Total	−11.96	−20.24	−22.67	−24.77	−27.43

The costs of this bill fall within budget function 550. This bill would reduce future federal liabilities through a change to an existing entitlement, and therefore could permit subsequent appropriation action

to reduce the necessary budget authority. The figures shown as "Required Budget Authority" represent that amount by which budget authority could be reduced below the level needed in the absence of enactment of H.R. 10909.

6. Basis for estimate: It is assumed that the authorization level for the inspection program stipulated in the bill will be fully appropriated and outlayed during 1979 and 1980. The Health Care Financing Administration (HCFA) estimates that approximately 3,000 laboratories not presently covered by existing interstate and/or Medicare regulations will require inspections at a cost of $1,000 per laboratory. This cost is for contractual services that will be administered by the local health services agencies.

All savings reflect the bill's impact on current policy projections for Medicare and Medicaid laboratory fees. The savings shown for the "exclusion of certain charges" provision are based on an estimate that total laboratory reimbursement under Medicare would be $57.6 million in 1979 under current policy. This figure was then inflated by 10 percent a year to account for the overall increase in laboratory services in fiscal years 1980–1983. (The 10 percent deflator was based on data from the Bureau of Labor Statistics on the average annual increase in laboratory costs.) Officials in both New York and New Jersey estimated that as much as 33 percent of current laboratory costs could be attributed to finder's fees and disproportionate costs. However, because of variations throughout the country in laboratory costs as well as difficulties in fully implementing this provision, a 10 percent savings was assumed for fiscal years 1979–1983. Although this provision also applies to Medicaid, it is assumed that the implementation of the competitive bidding process for laboratory services will almost completely eliminate finder's fees and disproportionate charges for Medicaid recipients.

To estimate the savings associated with the laboratory competitive bidding process, a federal Medicaid Laboratory fee base of $128 million was assumed for 1979 (based on data from the Senate Special Committee on Aging). A savings rate was derived from studies conducted in New York, New Jersey, and California on the effects of a competitive bidding process. Their reported savings ranged from 20 to 50 percent. A 25 percent savings rate was assumed for the first year during which competitive bidding would be in effect. Thereafter, it was assumed that as experience was gained with the competitive bidding process, the rate of growth in the laboratory fee base would decline from 15 percent a year to 10 percent. The result is that the net savings rate would grow to 30 percent by 1981. Time delays for implementing the bidding process were assumed to reduce the savings in 1979 by 50 percent. Full savings were assumed in outyears. It should also be noted that the program is only authorized through 1981.

The provision limiting percentage arrangements for hospital-based physicians would reduce payments to hospitals by the difference between what physicians are paid on a percentage basis and what they would be paid as salaried employees. Savings were assumed to apply to pathologists providing laboratory services in hospitals. It was estimated on the basis of data available from the American Medical Association, HCFA, and a recent study of hospital-based physicians done by Arthur Andersen and Co. for HCFA, that approximately 1,000

hospital pathologists would be affected by this provision. The Andersen study also provided data for 1975 on the difference in income between percentage basis and salaried pathologists in hospitals. This difference was adjusted for the overhead expenses assumed to be generated by the salaried pathologists and inflated by a factor for the growth in total hospital expenditures from 1975 to 1979. It was further assumed that only half of the apparent savings would be realized because of various adjustments likely to occur in the arrangements between the affected pathologists and their hospitals. Due to delays in implementation, only half of the potential savings in fiscal year 1979 are assumed to occur, whereas full savings occur in the outyears. The savings were assumed to grow at a rate consistent with the growth in total hospital expenditures.

7. Estimate comparison: None.

8. Previous CBO estimate: This cost estimate is a modification of the CBO cost estimate for H.R. 10909 as reported out by the Committee on Interstate and Foreign Commerce on March 24, 1978. It is different in that additional savings are generated by the provision disallowing percentage arrangements for hospital-based physicians which was added by the Subcommittee. In addition, this estimate modifies the earlier estimate by assuming that the costs of certain research activities for which no authorizations are given in the bill, will be covered by the budget for studies and demonstration projects falling under the authority of Section 1875 of the Social Security Act.

9. Estimate prepared by: Eric Wedum (225–7766).

10. Estimate approved by:

C. A. Nuckols,
(For James L. Blum,
Assistant Director
for Budget Analysis).

In compliance with clause 7 of rule XIII of the Rules of the House of Representatives, the following statement is made. Your committee concurs in the estimate furnished by the Director of the Congressional Budget Office relative to the cost impact of H.R. 10909 as amended.

V. Other Matters to be Discussed Under the House Rules

VOTE OF THE COMMITTEE

In compliance with subdivision (B) of clause 2(l)(2) of rule XI of the Rules of the House of Representatives, your committee reports that H.R. 10909 was ordered favorably reported by a voice vote.

OVERSIGHT FINDINGS

In compliance with subdivision (A) of clause 2(l)(3) of rule XI of the Rules of the House of Representatives, your committee reports that oversight activities with respect to this program have been conducted by several committees of the Congress, including your committee, in connection with consideration of fraud and abuse legislation and legislation relating to the medicare program. Oversight activities of a similar nature have been conducted by the Committee

on Interstate and Foreign Commerce. Your committee has not received oversight findings with respect to this program from the Committee on Government Operations.

NEW BUDGETARY AUTHORITY AND TAX EXPENDITURES

In compliance with subdivision (B) of clause 2(l)(3) of rule XI of the Rules of the House of Representatives, your committee states that H.R. 10909 provides authorizations of appropriations of $3 million per year for fiscal years 1979, 1980, and 1981 for the purposes of providing assistance to states with primary enforcement responsibility and assisting states and public and nonprofit private entities participating in the administration of the program under agreements with the Secretary.

INFLATION IMPACT

Your committee anticipates that the enactment of H.R. 10909 will have an impact on inflation in the health care field by reducing laboratory charges and costs reimbursed by the medicare and medicaid programs. As noted in the Congressional Budget office report, the anticipated savings reflects the effect this legislation will have on laboratory charges.

VI. Section-by-Section Analysis

SHORT TITLE; TABLE OF CONTENTS

Section 1 of the bill consists of the bill's short title and table of contents. The short title of the bill is the "Clinical Laboratory Improvement Act of 1978".

FINDINGS

Section 2 of the bill consists of Congressional findings as follows:

(1) Clinical laboratories are a vital element of health care;

(2) Health Care will only be effective and of high quality if procedures used for clinical laboratory testing assure accurate and reliable results;

(3) It is essential that the consumers of health care be protected by requiring that all clinical laboratories comply with uniform standards to assure accurate and reliable testing;

(4) Testing in laboratories which do not comply with such standards can be performed at less expense, resulting in unfair competition with laboratories which do comply with such standards;

(5) Requiring that clinical laboratories in interstate commerce comply with such standards without requiring that other clinical laboratories comply with them will discriminate against and depress interstate commerce and adversely burden, obstruct and affect such commerce;

(6) All clinical laboratory testing is either in interstate commerce or substantially affects such commerce; and

(7) Consequently, regulation by the Secretary of Health, Education, and Welfare in cooperation with the States as contemplated by this Act is appropriate to effectively regulate interstate commerce.

These findings emphasize the importance of accurate and reliable

clinical laboratory testing, emphasize the competitive disparities which would exist if only interstate laboratories were regulated, and indicate Congress' clear intent that the Commerce Clause be used to reach intrastate activities that affect interstate commerce. See *United States* v. *Wrightwood Dairy Co.* 315 U.S. 110 (1942), *Wickard* v. *Filburn*, 317 U.S. 111 (1942) and *Fry* v. *United States*, 421 U.S. 542 (1975). Thus, Congress is invoking its authority under the Commerce Clause to include intrastate activities within the reach of Federal regulation because the activities implicate interstate commerce. See generally *Heart of Atlanta Motel* v. *United States*, 379, U.S. 241, 249–258 (1964).

Title I of the bill consists of Public Health Service Act Amendments and Clinical Laboratory Studies.

Section 101 of the bill amends part H of title III of the Public Health Service Act (hereinafter, the "Act") to entitled such Part "Clinical Laboratories" and add the following new sections:

DEFINITIONS

New section 370 of the act consists of definitions of the terms "laboratory" and "clinical laboratory" and the term "interstate commerce".

Under this section, the terms "laboratory" and "clinical laboratory" are defined as any facility or identifiable part of a facility for examining materials derived from the human body for the purpose of diagnosis, prevention or treatment of disease or for assessing human health. The definition differs from existing law in that collection stations are included within the new definition. The bill specifically exempts blood banks from the definition of "laboratory" and "clinical laboratory" because blood banks are, in the opinion of the committee, effectively regulated by the Food and Drug Administration under other sections of the Public Health Service Act.

The committee does not intend that the definition be construed as including entities engaged in the manufacture, processing or repair of orthodontic corrective appliances, prosthetic dental appliances, ceramic or plastic teeth encapments, cast metal dental appliances, dental inlays, dental bridges, similar types of oral restorations not involving the examination or treatment of human tissue, even though such entities are generally referred to as commercial dental laboratories.

The term "interstate commerce" is defined to mean (1) trade, traffic, commerce, transportation, transmission or communication between any State and any place outside such State or (2) within the District of Columbia.

NATIONAL STANDARDS

New section 371(a) of the act provides that, within 210 days of the date of enactment of the proposed legislation, the Secretary, after reasonable opportunity for consultation with professional entities, shall publish proposed national standards for clinical laboratories. Within one year after such date of enactment, the Secretary is required to promulgate the standards with such modifications as he deems appropriate. These standards are to take effect upon their promulgation. The standards may be amended by the Secretary.

New section 371(b) of the act provides that national standards be designed to assure consistent performance by clinical laboratories of accurate and reliable laboratory tests and other procedures and services and shall (1) require laboratories subject to the standards to maintain appropriate quality control programs; (2) require such laboratories to maintain such records, equipment and facilities as may be necessary for the proper and effective operation of the laboratories; (3) require satisfactory performance by laboratories on periodic proficiency tests; (4) prescribe qualifications for directors and supervisory personnel of, and technologists employed in, such laboratories (which qualifications may not be limited solely to educational requirements, must include appropriate combinations of education, training, experience and examination requirements and must be designed to insure the continued competence of such personnel); (5) require supervisory personnel to evaluate, in accordance with guidelines prescribed by the Secretary, the proficiency of technicians employed in such laboratories; (6) require laboratories to provide assurances satisfactory to the Secretary that directors, supervisory personnel and technologists, will meet applicable personnel qualification requirements and all technologists and technicians will, where appropriate, perform their duties under supervision and only those duties for which they are found qualified, either under personnel qualifications or through their evaluation by supervisory personnel; and (7) includes such other requirements as the Secretary determines necessary to assure consistent performance by laboratories of accurate and reliable services.

The term "technologist" is defined as an individual employed in a laboratory who in performing services is required to exercise independent judgment. The term "technician" is defined as a person employed in a laboratory who is not required to exercise independent judgment in such employment.

New section 371(c) of the act provides that national standards may vary on the basis of the type of services performed by laboratories or the purposes for which they are performed.

In adopting this subsection, the committee recognized that variances in national standards are appropriate, depending upon the type of function or functions to be performed by the various laboratories in question. Some of the standards appropriate to a central hospital laboratory or independent laboratory created and operated to perform a variety of procedures or services may not necessarily be appropriate to single- or limited-function laboratories created and operated to perform tests in connection with a particular kind of patient care. Examples of the latter types of laboratories are blood-gas laboratories and acute intensive care laboratories, normally located close to the actual site of patient care and normally operated by a licensed physician who may also be the medical director of the hospital's unit for that type of care.

New section 371(d) of the Act provides that within one year of the date of enactment of the proposed legislation, the Secretary, in consultation with appropriate professional organizations, shall develop standards for proficiency testing of clinical laboratories subject to national standards. These proficency testing standards (1) must require testing to be administered at least annually; (2) must require a system

of on-site testing of the laboratory's proficiency in the examination of specimens which system shall comply with the procedural safeguards for inspections prescribed under section 376(b); and (3) may provide for a system of testing under which the laboratory is not informed that its proficiency is being tested (which system is commonly referred to as "blind proficiency testing").

APPLICATION OF NATIONAL STANDARDS

New section 372(a) of the act provides that national standards shall be administered and enforced by the Secretary and shall (except as noted below in the descriptions of subsections (b), (c), and (d)) apply to each clinical laboratory engaged in business in interstate commerce and apply to any other clincial laboratory located in a State which does not have primary enforcement responsibility (described below).

New section 32(b) of the act requires the Secretary, upon request of a State which has primary enforcement responsibility for the regulation of clinical laboratories, to authorize such State to regulate under the standards of the State, laboratories engaged in interstate commerce which are located or doing at least 10 percent of their business within the State.

New section 32(c) of the act provides that except as provided in section 103(a) of the bill (described below and relating to the study of physician office laboratories), national standards do not become applicable to clinical laboratories not engaged in interstate commerce until 2 years following the date that such standards take effect. In addition, it provides that during the 2-year period beginning on the date that national standards are first made applicable to laboratories (which date would be, in the case of interstate laboratories, the date on which standards take effect and, in the case of intrastate laboratories, 2 years after such date unless such laboratory is subject to section 103(a)(2) of the bill) the provisions of standards prescribing qualifications for supervisory personnel or for technologists (or both) shall not apply to a laboratory which (1) the Secretary determines is located in a rural area in which individuals with such qualifications are not available, (2) performs services solely for hospitals and health personnel located within the rural area, (3) provides the Secretary satisfactory assurances that it will take such actions as may be necessary to train individuals to meet such qualifications or to employ individuals with such qualifications.

The committee has adopted this provision in the recognition that rural hospital laboratories have special needs. The committee is aware of the inability of some rural hospitals to attract personnel with formal educational qualifications and believes that this provision, coupled with the requirement of section 371(b)(1)(D)(ii) that personnel qualifications must include appropriate combinations of education, training, experience, and examination requirements, will accommodate the special needs of rural areas with respect to personnel qualifications. There may well be other special needs of rural areas that should be met by flexible regulations. If this is the case, then, consistent with accuracy and reliability of test results, such needs should be addressed by the Secretary.

Further, this subsection exempts clinical laboratories located in the office of a licensed physician, dentist, or podiatrist, or a group of such practitioners, and in which the only services which are performed are services performed by a practitioner in conjunction with the treatment of his patients, from the application of national standards.

In addition, except as provided under section 103 of the proposed legislation, the national standards for clinical laboratories do not apply to any clinical laboratory (1) which is located in the office of or supervised by a licensed physician, dentist or podiatrist, or group of not more than five such practitioners, (2) in which the only services which are performed are in connection with the treatment of the patients of such practitioner (or group), or in connection with services provided for such patients by a physician's assistant or nurse practitioner under the supervision of such practitioner or group, and (3) which is a participant in a proficiency testing program approved by the Secretary if such participation is required under section 103(b) of such act.

Many of the practitioners whose clinical laboratories will be eligible for exemption under this subsection practice, consistent with their respective State laws, with nurse practitioners and physician assistants. Often these nurse practitioners and physician assistants are in different geographical locations from the practitioners in order that they can serve patients who otherwise would not have easy access to practitioners. Because the committee is supportive of these relatively new professional relationships, it expanded the so-called physician office exemption to include clinical laboratories which are not in the office of practitioners but are at the separate location of the nurse practitioners or physician assistants who are being supervised by the practitioners. The only laboratory tests which are performed in these clinical laboratories are laboratory tests performed for patients who are being treated by the nurse practitioners or physician assistants.

The committee is concerned, however, that this exemption not be misused. The committee intends that the Secretary develop a mechanism by which assurances can be gained that such a clinical laboratory, which is located outside the office of practitioners, is used only to perform laboratory tests in connection with the treatment of patients of practitioners and their nurse practitioners or physician assistants, and that the practitioners exercise reasonable supervisory responsibility, even though not on-site at all times. The committee notes that the Secretary now has continuing relationships with some providers whose clinical laboratories will be eligible for this exemption. If, as with rural health clinics which are certified by the Secretary for participation in titles XVIII and XIX, there is a certification process in existence, the Secretary should use such process as a mechanism to gain assurances that the exemption is properly applied.

Further, under this subsection, the Secretary is required, upon application, to exempt from national standards, on such terms as may be appropriate, any laboratory in which the only services which are performed are services for biomedical and behavioral research. This provision was adopted by the committee in order to avoid a negative impact on the development and expansion of innovative techniques and laboratory technology. It is not the committee's intent to restrain

or inhibit clinical research or the transfer of basic research findings to clinical application. The committee understands that there are unique situations where clinical research and clinical care are performed by the same laboratory. Often a comparison needs to be made of an existing technique with a new research technique so as to validate the new against the old. Eventually these procedures are transferred to a clinical laboratory and become routine procedures. The committee also is aware that there are unusual diagnostic tests that are conducted by research laboratories because only they have the expertise to do so. These tests provide valuable medical care but are performed almost exclusively in research laboratories. So as not to restrict research laboratories from conducting these tests, the committee expects the Secretary to take these situations into account when setting standards for laboratories. However, in doing so, effective protection for patients and quality control should be provided and insured.

Finally, this subsection provides that except as provided under section 104(b)(2) of the proposed legislation (described below and relating to a study and report on highly specialized clinical laboratories) the national standards do not apply to highly specialized clinical laboratories engaged exclusively in the assessment of cardiac or pulmonary functions.

New section 372(d) of the act governs the applicability of national standards to Federal clinical laboratories. It provides that clinical laboratories under the jurisdiction of the Secretary and any other Federal clinical laboratories shall be subject to national standards unless (1) the laboratory is under the jurisdiction of the armed forces of the United States or the Administrator of Veterans' Affairs, or (2) the agency which has jurisdiction over the laboratory has in effect standards for the laboratory which are no less stringent than the national standards. It provides that the Secretary shall bring national standards to the attention of the Secretary of each military department and the Administration of Veterans' Affairs so that such standards may be considered and applied as appropriate by such persons to laboratories under their jurisdiction.

New section 372(e) of the act prohibits a State or political subdivision from adopting or continuing in effect requirements (other than personnel licensing requirements and requirements applicable to laboratories under a certificate of need program) which are applicable to clinical laboratories and different from national standards unless the State has primary enforcement responsibility (described below).

New section 372(f) of the act provides that any clinical laboratory which is engaged in business in interstate commerce shall, during the period beginning on the date of the enactment of the proposed legislation and ending on the date such laboratory is required to have in effect a license issued under the provisions of the new legislation, comply with licensing requirements in effect under section 353 of the Public Health Service Act before such date of enactment.

LICENSES

New section 373(a) of the act requires the Secretary to establish a system for the licensure of clinical laboratries subject to national

standards. It provides that a license is to specify the categories of tests and procedures which a laboratory may perform and is to be valid for such period as the Secretary may prescribe, but not in excess of 36 months. It authorizes the Secretary to require a fee for the issuance or renewal of a license, but in an amount not to exceed $500. Such fees may vary based by the volume of tests or procedures performed by clinical laboratories. Obviously, for example, fees for collection stations should be less than those for laboratories that provide a comprehensive range of services.

New section 373(b) of the act requires that the system for licensure of clinical laboratories established by the Secretary must include the following conditions to the issuance or renewal of the license: (1) submission of an application, (2) a determination that the applicant meets national standards, and (3) submission by the applicant to the Secretary and to the health systems agencies serving the area in which the applicant is located of a schedule of fees the applicant charges for laboratory services and such information as may be necessary to disclose any contractual relationships in effect between the applicant and physicians and other health professionals respecting the laboratory's services and the terms of any contracts between the applicant and such person. It provides that a health system agency may not disclose the identity of any person for whom an applicant for a license performed services except in response to a request of an officer or employee of the United States or of a State in conjunction with the enforcement of Part H of the Public Health Service Act or of Federal or State criminal law. Further, a health system agency is not authorized to disclose any contractual relationships except (1) contractual relationships between the applicant and any physician for the performance of services if the applicant receives compensation under titles XVIII or XIX of the Social Security Act and (2) contractual relationships in response to a request of an officer or employee of the United States or state in connection with enforcement of Part H of the Public Health Service Act or a Federal or State criminal law.

New section 373(c) of the act contains provisions with respect to the suspension and revocation of licenses, and eligibility to apply for a license.

First, it provides that if the Secretary finds, after notice and opportunity for hearing, that (1) a laboratory is not in compliance with national standards or (2) the owner or operator of the laboratory has failed to comply with reasonable requests of the Secretary for information or material necessary to determine the laboratorys' continued eligibility for its license or continued compliance with national standards or (3) the owner or operator has refused a request of the Secretary or other Federal officer or employee designated by the Secretary for pemission to inspect the laboratory and its operations and pertinent records at any reasonable time, the Secretary may suspend the laboratory's license until the owner or operator demonstrates that the laboratory is in compliance with national standards or that such tests will be complied with, as the case may be.

Second, this subsection provides that if the Secretary finds, after reasonable notice and opportunity for hearing, that the owner or operator of a clinical laboratory (1) has been guilty of misrepresenta-

tion in obtaining a license, (2) has engaged or attempted to engage in, or repersented himself as entitled to perform, laboratory tests or procedures not authorized by the license, (3) has engaged in a billing practice under which charges for laboratory services for a patient on whose behalf reimbursement for such charges is provided under a program receiving Federal financial assistance are made at a higher rate than charges for such services provided a patient for whom such reimbursement is not made, (4) has offered, paid, solicited or received any renumeration (including any kickback, bribe, finder's fee, or rebate, but excluding any discount or other reduction in price and excluding any amount paid by an employer for employment in the provision of the services) directly or indirectly, overtly or covertly, in cash or kind in connection with the provision of clinical laboratory services or (5) has engaged in any false, fictitious or fraudulent billing practice for the purpose of obtaining payment under any program the funds for which are provided in whole or part by the United States, the Secretary may revoke the license for the remainder of its term or make the owner or operator ineligible to apply for a license for a period not to exceed 2 years, or take both such actions. Differences in administrative costs related to receiving reimbursement for the provision of services are not to be considered in determining whether the owner or operator has engaged in a discriminatory billing practice.

New section 373(d) of the act requires that any person who is convicted under the provisions of section 375 of the Public Health Service Act as added by this bill (relating to operating a clinical laboratory without a proper license) or convicted under section 1877(b) or 1909 (b) of the Social Security Act (the "anti-fraud" provisions of the Medicare and Medicaid laws) shall not be eligible to apply for a license for a clinical laboratory during the ten-year period beginning on the date that such person's conviction became final and further requires that the license for the laboratory involved in the violation shall be revoked.

New Section 373(e) of the act relates to judicial review of final action with respect to revocation or suspension of, or ineligibility to apply for, a license. It authorizes a person aggrieved by such action to file a petition for judicial review of the action in the United States Court of Appeals for the circuit where the person resides or has his principal place of business at any time within 60 days after the date of the action. It requires that a copy of such petition be transmitted by the clerk of the court to the Secretary or to the officer designated by the Secretary for such purposes. Upon receipt of the petition, the Secretary is required to file in the court the record upon which his action was based, as provided in section 2112 of title 28, United States Code (relating to the filing and contents of Federal agency records to be reviewed in courts of appeals). It provides that if the petitioner applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that such evidence is material and that there were reasonable grounds for failure to adduce the evidence in the proceeding before the Secretary, the court may order such additional evidence, as well as evidence in rebuttal of the additional evidence, to be taken before the Secretary and to be adduced upon the hearing. The Secretary is authorized to modify his findings as to the facts or make new findings by reason of such additional evidence and file such modi-

fied or new findings and any recommendations for the modification or setting aside of his original action with the return of the additional evidence. Further, this subsection requires that upon the filing of the petition for review, the court of appeals shall have jurisdiction to affirm the action or to set it aside in whole or in part, temporarily or permanently. It requires that the findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

PRIMARY ENFORCEMENT RESPONSIBILITY

New section 374(a) of the act provides the State has primary enforcement responsibility during any period for which the Secretary determines, pursuant to regulations, that the State (1) has adopted (a) standards applicable to clinical laboratories which are no less stringent than national standards and (b) a system for the licensure of laboratories which meets the requirements set forth below with respect to primary enforcement responsibility and which includes provisions respecting submissions of information to health systems agencies for the health service area in which applicants are located or doing at least ten percent of their business which provisions are no less stringent than the licensing provisions set forth elsewhere in this legislation, and includes provisions respecting the suspension, revocation, and eligibility for licenses which are no less stringent than provisions set forth in the bill with respect to laboratories subject to national standards; (2) is able to enforce such State's standards; (3) will keep such records and reports with respect to licensing and enforcement as the Secretary may require by regulation; (4) if it permits exemptions from requirements, permits exemptions under conditions and in a manner no less stringent than those applicable in instances in which a laboratory is subject to national standards; (5) has adopted and can implement adequate procedures for control of health hazards resulting from clinical laboratories; (6) has designated a single agency to enforce its standards and administer its licensure system; and (7) will coordinate with other States in order to avoid duplicate requirements.

New section 374(b) of the act provides that, for the purpose of primary enforcement responsibility, a State system for the licensure of clinical laboratories (1) shall prescribe that licenses shall be valid for a period not in excess of 36 months and may require a fee for the issuance or renewal of a license in an amount not in excess of $500, (2) may provide for variances in such fees based upon volume of tests or procedures, and (3) must provide that licenses issued for clinical laboratories shall specify the categories of tests and procedures which the laboratory is authorized to perform.

New section 374(c) of the act provides that clinical laboratories subject to regulation by a State which has primary enforcement responsibilities are all clinical laboratories located within the State which are not engaged in business in interstate commerce other than certain Federal clinical laboratories which are exempt pursuant to the provisions of subsection 372(d), and, if authorized under the provisions of section 372(b), interstate laboratories located or doing business within the State (except laboratories exempt under section 372(d).

New section 374(d) of the act provides that the Secretary shall, within one year of the date of enactment of the bill, propose regulations which prescribe the manner in which a State may apply to the Secretary for determination that the requirements relating to primary enforcement responsibility are satisfied, the manner in which the determination shall be made, the period for which the determination shall be effective, and the manner in which the Secretary may determine that such requirements are no longer met. It requires the Secretary, at least every two years, to review the clinical laboratory regulatory activities of a State with primary enforcement responsibility to determine if the State continues to meet such requirements. It provides that such regulations require that, before any determination of the Secretary that a State does not have or no longer has primary enforcement responsibility becomes effective, the Secretary must notify the State of the determination and the reasons therefor, provide an opportunity for a public hearing on such determination, and, in the case of a determination that the requirements are no longer being met by a State, prescribe the period in which the State must comply with the requirements in order to retain its primary enforcement responsibility. Regulations with respect to primary enforcement responsibility must be promulgated within 90 days of their publication in the Federal Register. Following their promulgation, the Secretary is required to promptly notify in writing the chief executive officer of each State. The notification must contain a copy of the regulations as well as specify a State's authority when it is determined to have primary enforcement responsibility. Finally, this subsection requires that within 90 days of the date on which an application for a determination as to whether a State has primary enforcement responsibility has been submitted, the Secretary is required to make such determination or deny the application and notify the applicant in writing of the reasons for the denial.

PROHIBITED ACTS

New section 375(a) of the act prescribes prohibited acts with respect to clinical laboratories and penalties for performing such acts. This subsection provides that any person who solicits or accepts, directly or indirectly, any specimen for a laboratory test or other procedure by a laboratory which is required to be licensed by the Secretary and which does not have such a license in effect or which is not authorized by its license to perform such test or procedure, shall be fined not more than $10,000 or imprisoned for not more than one year, or both.

New section 375(b) of the act prohibits clinical laboratories required to have in effect a license issued by the Secretary or by a State with primary enforcement responsibility which do not have such a license from receiving a grant, contract or other form of financial assistance under the Public Health Service Act or charge or collect for laboratory services for an entity which received a grant, contract or other form of assistance under the Public Health Service Act. In addition, the charges of such a laboratory may not be included in determining Federal payments under title XVIII of XIX of the Social Security Act.

ENFORCEMENT

New section 376(a) of the act provides authority to the Secretary in connection with enjoining activities of clinical laboratories. It authorizes the Secretary, when he has reason to believe that continuation of any activity by a clinical laboratory required to be licensed by him would constitute a significant hazard to the public health, to bring suit in the United States district court of the district in which the laboratory is situated to enjoin continuation of the activity and requires the court, upon proper showing, to issue a temporary injunction or temporary restraining order against continuation of such activity, without bond, pending issuance of a final order.

New section 376(b) of the act provides inspection authority for purposes of enforcement of the proposed legislation. It authorizes individuals designated by the Secretary to enter and inspect any clinical laboratory subject to national standards. A separate notice is to be given for each inspection, but not each entry made during an inspection. Any inspection is to be made during the normal business hours of the laboratory being inspected and the inspection may extend only to pertinent equipment, materials, containers, records, files, papers (including financial data, sales data and pricing data) processes, controls, facilities and all other things in a laboratory bearing upon whether it is being operated in compliance with national standards. Upon completion of any inspection and prior to leaving the premises, the inspector is required to give to the owner, operator or agent in charge a preliminary report which summarizes any conditions or practices observed which in the judgment of the inspector indicate a violation of national standards. The inspector must also prepare a written final report of his findings and send it to the owner, operator or agent within 30 days of completion of the inspection. No individual designated to enter a laboratory and conduct an inspection shall be required to obtain a search warrant prior to entering the laboratory and conducting any inspection which is authorized by the subsection. Finally, this subsection provides that for the purpose of determining whether States with primary enforcement responsibility continue to meet requirements for primary enforcement responsibility, the Secretary may designate individuals to conduct inspections of laboratories not subject to national standards to determine if they are in compliance with applicable State standards. Each such inspection is to be carried out in accordance with the limitations with respect to notice, hours, and things that may be inspected described above.

New section 376(c) of the act relates to protection of employees of clinical laboratories. This subsection provides that no employer may discharge or otherwise discriminate against any employee with respect to compensation or the terms, conditions or privileges of employment because the employee or a person acting pursuant to the request of the employee has (1) commenced or caused to be commenced a proceeding under new section 373(c), 375(a) or 376(a) of the act or a proceeding by a state in carrying out its primary enforcement responsibility; (2) testified, or is about to testify, in any such proceeding; or (3) assisted or participated, or is about to assist or partici-

pate, in such proceeding or in any other action to carry out the purpose of new part H of the act.

Further, the subsection provides that any employee who believes that he has been discharged or otherwise discriminated against by a person in violation of the provisions outlined above may, within 30 days after the alleged violation occurs, file a complaint with the Secretary of Labor (hereinafter, in the description of this subsection only, referred to as the "Secretary") alleging such discharge or discrimination and further provides that, upon receipt of such complaint, the Secretary shall notify the person named in the complaint of its filing. Upon receipt of such a complaint, the Secretary is required to conduct an investigation of the violations alleged and, within 30 days of receipt of the complaint complete the investigation and notify the complainant in writing, as well as the person alleged to have committed the violation, of the results of the investigation. Within 90 days of receipt of the complaint, unless the proceeding has been terminated by the Secretary because of a settlement entered into by the Secretary and the person alleged to have committed the violation, the Secretary is required to issue an order, made on the record and after opportunity for hearing, which either provides relief or denies the complaint. A settlement terminating a proceeding may not be entered into by the Secretary without the participation and consent of the complainant.

If the Secretary determines that a violation of this subsection has occurred, he must: (1) require the person who committed the violation to take affirmative action to abate the violation, (2) require such person to reinstate the complainant to his former position together with the compensation and terms, conditions and privileges of the complainant's employment (including back pay), and (3) order the award of compensatory damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the amount of all costs and expenses reasonably incurred by the complainant for or in connection with the bringing of the complaint.

The subsection provides for judicial review of any order described above. Judicial review is to be obtained in the United States court of appeals for the circuit in which the violation allegedly occurred. The petition for review must be filed within 60 days from the issuance of the order of the Secretary and review is to be under the conditions of chapter 7 of title 5 of the United States Code (applicable provisions of the Administrative Procedure Act). Any order of the Secretary with respect to which review may be obtained under these provisions shall not be subject to judicial review in any criminal or other civil proceeding.

Further, this subsection provides that whenever a person has failed to comply with an order issued by the Secretary of Labor, the Secretary shall file a civil action in United States district court for the district in which the violation was found to occur in order to enforce the order. In such actions, the district courts shall have jurisdiction to grant appropriate relief including injunctive relief and compensatory and exemplary damages. Such actions must be heard and decided expedi-

tiously. Further, this subsection provides that any non-discretionary duty imposed by this subsection is enforceable in mandamus proceedings brought under section 1361 of title 28, United States Code (relating to actions to compel officers of the United States to perform their duties).

Finally, this subsection provides that its terms are not applicable with respect to any employee who, acting without direction from his employer (or any agent of the employer) deliberately causes a violation of any requirement of new Part H of the act or a requirement of a State with primary enforcement responsibility.

AGREEMENTS AND ASSISTANCE

New section 377(a) of the act authorizes the Secretary and any State which has primary enforcement responsibility to enter into agreements with qualified public or non-profit private entities which have adopted laboratory standards at least as stringent as those in effect under new section 371 of the act (or, in the case of agreements to be entered into by a State, at least as stringent as those in effect in such State) under which agreements such entities would (1) make such inspections as the Secretary or the State may require to determine if clinical laboratories are in compliance with applicable standards, (2) administer such proficiency tests as the Secretary or the State may require for clinical laboratories or such examinations of laboratory personnel as they may require, or (3) do any combination of the activities described above. An agreement entered into under this subsection may provide for financial assistance to the entity to assist it in meeting the costs of conducting activities prescribed for it by the agreement.

New section 377(b) of the act provides that if the Secretary has entered into an agreement under section 1864(a) of the Social Security Act for the enforcement of section 1861 of such act with respect to clinical laboratories by a State which does not have primary enforcement responsibility, the Secretary may enter into an agreement with a State for the enforcement within such State of the requirements of national standards with respect to laboratories not subject to requirements of such section 1861. Such an agreement may provide for financial assistance to the State to assist it in meeting its costs of enforcing the requirements for national standards.

New section 377(c) of the act authorizes the Secretary to enter into agreements with States with primary enforcement responsibility under which agreements financial assistance will be provided to the States to assist them in meeting the costs of administering and enforcing the programs for the regulation of clinical laboratories which are not covered under the agreements authorized by Title XVIII of the Social Security Act. In addition, this subsection authorizes the Secretary to provide technical assistance to any State to assist it in meeting requirements relating to primary enforcement responsibility.

New section 377(d) of the act authorizes appropriations of $3 million per year for fiscal years 1979, 1980, and 1981 for the purpose of agreements authorized by subsections (a), (b), and (c) of section 377, described above.

ANNUAL REPORT

New section 378(a) of the act requires that not later than the first January 1 which occurs more than nine months after national standards first take effect, and each succeeding January 1, the Secretary shall make a report to Congress respecting to the accuracy of tests and procedures performed by clinical laboratories during the preceding fiscal year and evaluating the effect of the costs of clinical laboratory tests and procedures on the overall cost of health care services and the relation of the costs of such tests and procedures to the costs of health care services for which the services are conducted.

New section 378(b) of the act would repeal subpart 2 of part F of title III of the act (the existing authority with respect to clinical laboratories).

New section 378(c) of the act is a technical amendment which preserves existing section 372(e) of the Public Health Service Act (relating to assistance to the Alaskan Mental Health Program), which section is repealed by the amendments made to Part H of the act.

STUDY RESPECTING REQUIREMENTS FOR LABORATORIES AND LABORATORY PERSONNEL

Section 102 of the bill requires that there be conducted a study of procedures and certification of laboratory personnel. This section requires the Secretary of Health, Education, and Welfare, in cooperation with appropriate public and private entities, to conduct a study of (1) existing voluntary certification standards and state licensure laws for clinical laboratory supervisors, technologists, and technicians and (2) qualifications of entities that certify such personnel as qualified to perform laboratory procedures in clinical laboratories licensed under section 373 of the Public Health Service Act. This study must include (1) an assessment of the need for certification of such personnel pursuant to national standards, (2) development of national standards which the Secretary determines should be used as guidelines for entities which certify such personnel, (3) the determination of the numbers of technical laboratory personnel who would meet standards developed by the Secretary and a projection of the numbers of such personnel in calendar years 1980, 1985 and 1990, (4) an analysis of the effect on costs of laboratory tests and procedures and the quality of such tests and procedures of a requirement that only laboratory personnel which meet such standards meet qualifications necessary for a laboratory to be licensed under section 373 of the Public Health Service Act, and (5) an analysis of the various entities who certify laboratory personnel including an analysis of the need for participation in certification procedures by numbers of the public and the financial interests of such entities in clinical laboratories. The Secretary is required to submit to the Congress the results of this study and recommendations for legislation as the Secretary considers necessary within one year of the date of enactment of the bill.

STUDY AND REPORT ON PRACTITIONERS' OFFICE LABORATORIES

Section 103(a) of the bill requires the Secretary to conduct or arrange to have conducted a study concerning laboratories located in the offices of physicians, dentists, or podiatrists which have been exempted from national standards under section 371 of the act. The study is to assess the quality of clinical laboratory services provided by such laboratories and is to include an evaluation of (1) proficiency testing programs in which such laboratories participate and the effect such participation by the laboratories in such proficiency testing programs has on the medical reliability of the results of tests performed by them and (2) quality control programs, personnel qualifications, and proficiency of laboratory personnel and other factors bearing on the medical reliability of tests and procedures performed by laboratories so exempted. Any laboratory which refuses to participate in the study shall be required to meet the national standards in effect for clinical laboratories engaged in business in interstate commerce.

Section 103(b) of the bill requires the Secretary, within 1 year of the date of enactment of the new act, to report to the Congress the results of the evaluation. If the Secretary finds on the basis of the evaluation that the results of tests performed by laboratories participating in proficiency testing programs are, as determined on a statistical basis, significantly more reliable than the results of tests performed by laboratories which are not participants in proficiency testing programs, the Secretary may by regulation as a condition to the exemption of physician office laboratories from national standards require that such laboratories participate in proficiency testing programs approved by the Secretary. Such regulation shall prescribe procedures and standards for the approval of proficiency testing programs and be promulgated only after affording opportunity for an oral hearing.

Within 2 years of the date of enactment of the new act, the Secretary is required to report to the Congress the results of the evaluation of quality control programs, personnel qualifications, and proficiency of laboratory personnel. In the report the Secretary is to recommend whether physician office laboratories should be required as condition to such exemption to have laboratory procedure manuals or other items or procedures bearing on the medical reliability of tests and procedures performed by such laboratories.

STUDY AND REPORT ON HIGHLY SPECIALIZED CLINICAL LABORATORIES

Section 104(a) of the bill requires the Secretary to conduct or arrange to have conducted a study to assess the quality of the tests and other procedures and services provided by highly specialized laboratories, including those laboratories exempted from national standards by section 372(c)(5) of the new act. The study is to be carried out in consultation with appropriate professional organizations and is to include an evaluation of personnel qualifications, quality control programs, proficiency of laboratory personnel and other factors bearing upon the medical reliability of the tests, procedures and services performed by the laboratories studied.

Section 104(b) of the bill requires the Secretary, within 2 years of the date of the enactment of the new act, to report the results of the study described above and include in the report such recommendations for legislation as the Secretary determines appropriate. Within 2 years of the date of the enactment of the new act, the Secretary is required to promulgate regulations to make national standards applicable to highly specialized clinical laboratories, with such modifications as the Secretary may prescribe.

STUDY OF CLINICAL LABORATORY SERVICES

Section 105(a) of the bill requires the Secretary, during the period beginning on the date of the enactment of this act and ending on the date national standards first take effect, and again during the 2-year period beginning on the date the standards take effect, to conduct a study to determine the quality of the tests, procedures and other services provided by clinical laboratories during each such period and the cost of such services during both such periods. The Secretary is required to compare the data on the quality and cost of the services provided in the two period study to determine the effect of the amendments made by the act on the quality and cost of clinical laboratory services.

Section 105(b) of the bill requires that data on the quality and cost of laboratory services shall be assembled under the study on the basis of (1) the size and type of clinical laboratories studied and the categories of persons for whom the services were provided, (2) the volume of services provided, (3) the qualifications and experience of the personnel that performed or supervised the services studied, (4) the protocols followed by the laboratories in providing such services, and (5) the States or other geographic regions in which such services were provided.

Section 105(c) of the bill requires the Secretary to make a preliminary report to the Congress on the results of the study not later than ninety days after expiration of the first period study and a final report on the study (together with any recommendations for legislation) not later than 180 days after the expiration of the second period study.

The purpose of this section is to insure that sufficient data is collected to make possible a determination of the effectiveness of the Clinical Laboratory Improvement Act of 1978. Accordingly, a representative selection of laboratory tests should be evaluated, and the study should provide a comprehensive, nationwide statistical profile of the clinical laboratory industry, with the exception of physicians' office laboratories. The data collected should be comprehensive in scope and organized in such a way as to permit a comparison of the quality and charges of different laboratories not only by type, but by volume, geographic region, qualifications of personnel, composition of clientele, regulatory environment, and other relevant criteria. The study should be conducted by researchers who are not connected with the administration or implementation of the act.

Title II of the bill consists of amendments to the Social Security Act, and authorized studies relating to those amendments.

Section 201 of the bill amends section 1124(a)(1) of such act (relating to disclosure of ownership information) to require an independent clinical laboratory to furnish such information and access to its records as the Secretary may require to determine whether and in what amounts the laboratory has charged a physician for laboratory services performed by the laboratory.

Section 202(a) of the bill provides that payments under medicare to physicians for laboratory tests included in their bills shall be determined as follows:

(i) if the physician's bill indicates that the physician or another physician with whom the physician shares his practice personally performed or supervised such services, the payment shall be the reasonable charge for the test (less the applicable deductible and coinsurance amounts);

(ii) if the bill indicates that the services were performed by a laboratory and specifies the amount the laboratory charged the physician who submitted the bill, payment shall be the lower of (a) the reasonable charge of the laboratory for such services, or (b) the amount the laboratory charged the physician for the test, plus a nominal fee (where the physician bills for such a service) to cover the physician's costs in collecting and handling the sample on which the test was performed (less the applicable deductible and coinsurance amounts);

(iii) if the bill does not indicate who performed the services or indicates the services were performed by a laboratory which is not identified, payment shall be at the charge estimated to be the lowest charge at which the test could have been secured by a physician from a laboratory serving the locality (less the applicable deductible and coinsurance amounts).

Section 202(b) of the bill makes conforming changes to insure that payment for laboratory services under Medicare will not be made unless the laboratory meets applicable State and Federal requirements imposed by the proposed legislation.

Section 202(c) of the bill provides that if the Joint Commission on Accreditation of Hospitals imposes standards for hospital laboratories which are at least equivalent to the national standards, the Secretary (or the State, in the case of a State with primary enforcement responsibility) may deem that the hospital laboratory meets the Medicare licensure requirements.

Section 202(d) of the bill makes several technical corrections in section designations.

Section 203(a) of the bill authorizes for a three year period, states to make arrangements for competitive bidding for the provisions of clinical laboratory services under the Medicare program if the Secretary finds that (i) adequate services will be available under the arrangements (ii) laboratory services will be provided only by laboratories which meet the requirements of the proposed legislation, and which do no more than 75 percent of their business with Medicare and Medicaid, and (iii) charges will be made at the lowest rate charged by the provider for comparable services. Competitive bidding arrangements are to be evaluated by the Secretary, who is to transmit the evaluation and legislative recommendations to the Secretary within 24 months from the date of enactment.

Section 203(b) of the bill makes conforming changes to insure that payment for services under Medicaid will not be made unless the laboratory meets applicable requirements of the proposed legislation.

Section 203(c) of the bill requires that payments for laboratory services under Medicaid not exceed the lowest amount charged for such service by the provider.

Section 203(d) of the bill requires that if the Medicaid State plan authorizes payment to a physician for laboratory services (or to a physician sharing his or her practice) which the physician did not personally perform or supervise, payment will be made in accordance with the new Medicare requirements described in 15 above. Appropriate transitional provisions are included.

Section 204 of the bill amends title XI of the Social Security Act by adding a new section 1127 which provides that (a) if a physician performs a professional service in a hospital and the hospital's payment to the physician for the service is based on a percentage of the hospital's charges for the service, no part of such a payment shall be considered reasonable for the purpose of reimbursement under titles V, XVIII, or XIX, to the extent that the part exceeds the sum of (1) the compensation which would reasonably have been paid by the hospital to the physician performing the service and additional costs that would have been incurred by the hospital, if the service had been performed by the physician in an employment relationship with the hospital, and (2) the cost of such other reasonable expenses incurred by the physician in performing the service, as the Secretary determines to be appropriate; and (b) if a physician furnishes professional services in a hospital to patients of the hospital and if these services are furnished in the hospital under a rental or lease arrangement under which arrangement the hospital is paid an amount that is based (directly or indirectly) on a percentage, fraction, or proportion of the charges made for the services furnished, the amount that shall be treated as a reduction from the hospital's costs otherwise allowable under titles V, XVII, and XIX, with respect to its receipt of payments under the arrangement, shall be the greater of (1) the amount paid to the hospital under the arrangement with respect to the services furnished or (2) the amount by which the charges made by the physician for the furnishing of the services, exceeds the amount of the costs which would have been incurred for the furnishing of the services if they were furnished directly by the hospital through individuals who were all employed on a reasonable compensation basis by the hospital rather than under such arrangement.

Section 204 (b) and (c) of the bill provides that the new section 1127 shall apply to payments for professional services performed by physicians (and to payments received by a hospital with respect to those professional services which are performed in a hospital under a rental or lease arrangement) on and after the first day of the first calendar quarter that begins more than 60 days after enactment, except that if professional services are performed by a physician under a contract with a hospital (or if a hospital receives payment under a rental or lease arrangement) entered into before June 1, 1978, the new section 1127 shall apply to payments for services performed after

the date of termination of the contract or arrangement, or May 31, 1978, whichever occurs earlier.

Section 205 of the bill requires the Secretary, within 24 months of the effective date of the amendments made by section 202(a), to report to the Congress (1) the proportion of bills submitted under title XVIII for laboratory services which did not identify who performed the services; (2) the proportion of such bills with respect to which the amount paid was less than the amount that would otherwise have been payable in the absence of section 1842(h); (3) the average additional cost per laboratory test to patients resulting from reductions in payment; and (4) the average reduction in payment per laboratory test to physicians resulting from the application of section 1842(h).

VII. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown below using the following typographical devices (with "W & M" referring to the Committee on Ways and Means and "IFC" referring to the Committee on Interstate and Foreign Commerce):

Existing Law—

—in which no change is proposed by W & M or IFC, printed in roman.

—proposed to be omitted by both W & M and IFC, enclosed in black brackets, viz, [ ].

—proposed to be omitted only by IFC (and not by W & M), printed in ~~linetype.~~

—proposed to be omitted only by W & M (and not by IFC), enclosed in black parentheses, viz, ( ).

New Matter—

—proposed to be inserted by both W & M and IFC, printed in *italic.*

—proposed to be inserted only by IFC (and not by W & M), printed in ~~*italic linetype.*~~

—proposed to be inserted only by W & M (and not by IFC), printed in **boldface roman.**

Public Health Service Act

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

Part F—Licensing—Biological Products and Clinical Laboratories and Control of Radiation

Subpart 1—Biological Products

* * * * * * *

[SUBPART 2—CLINICAL LABORATORIES

[LICENSING OF LABORATORIES

[SEC. 353. (a) As used in this section—

[(1) the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the asessment of the health of, man;

[(2) the term "interstate commerce" means trade, traffic, commerce, transportation, transmission, or communication between any State or possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

[(b)(1) No person may solicit or accept in interstate commerce, directly or indirectly, any specimen for laboratory examination or other laboratory procedures, unless there is in effect a license for such laboratory issued by the Secretary under this section applicable to such procedures.

[(2) The Secretary shall by regulation exempt from the provisions of this section laboratories whose operations are so small or infrequent as not to constitute a significant threat to the public health.

[(c) A license issued by the Secretary under this section may be applicable to all laboratory procedures or only to specified laboratory procedures or categories of laboratory procedures.

[(d)(1) A license shall not be issued in the case of any clinical laboratory unless (A) the application therefor contains or is accompanied by such information as the Secretary finds necessary, and (B) the applicant agrees and the Secretary determines that such laboratory will be operated in accordance with standards found necessary by the Secretary to carry out the purposes of this section. Such standards shall be designed to assure consistent performance by the laboratories of accurate laboratory procedures and services, and shall include, among others, standards to assure—

[(i) maintenance of a quality control program adequate and appropriate for accuracy of the laboratory procedures and services;

[(ii) maintenance of records, equipment, and facilities necessary to proper and effective operation of the laboratory;

[(iii) qualifications of the director of the laboratory and other supervisory professional personnel necessary for adequate and effective professional supervision of the operation of the laboratory (which shall include criteria relating to the extent to which training and experience shall be substituted for education); and

[(iv) participation in a proficiency testing program established by the Secretary.

[(2) A license issued under this section shall be valid for a period of three years, or such shorter period as the Secretary may establish

for any clinical laboratory or any class or classes thereof; and may be renewed in such manner as the Secretary may prescribe. The provisions of this section requiring licensing shall not apply to a clinical laboratory in a hospital accredited by the Joint Commission on the Accreditation of Hospitals or by the American Osteopathic Association, or a laboratory which has been inspected and accredited by such commission or association, by the Commission on Inspection and Accreditation of the College of American Pathologists, or by any other national accreditation body approved for the purpose by the Secretary, but only if the standards applied by such commission, association, or other body in determining whether or not to accredit such hospital or laboratory are equal to or more stringent than the provisions of this section and the rules and regulations issued under this section, and only if there is adequate provision for assuring that such standards continue to be met by such hospital or laboratory; provided that any such laboratory shall be treated as a licensed laboratory for all other purposes of this section.

[(3) The Secretary may require payment of fees for the issuance and renewal of licenses, but the amount of any such fee shall not exceed $125 per annum.

[(e) A laboratory license may be revoked, suspended, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

[(1) has been guilty of misrepresentation in obtaining the license;

[(2) has engaged or attempted to engage or represented himself as entitled to perform any laboratory procedure or category of procedures not authorized in the license;

[(3) has failed to comply with the standards with respect to laboratories and laboratory personnel prescribed by the Secretary pursuant to this section;

[(4) has failed to comply with reasonable requests of the Secretary for any information or materials, or work on materials, he deems necessary to determine the laboratory's continued eligibility for its license hereunder or continued compliance with the Secretary's standards hereunder;

[(5) has refused a request of the Secretary or any Federal officer or employee duly designated by him for permission to inspect the laboratory and its operations and pertinent records at any reasonable time; or

[(6) has violated or aided and abetted in the violation of any provisions of this section or of any rule or regulation promulgated thereunder.

[(f) Whenever the Secretary has reason to believe that continuation of any activity by a laboratory licensed under this section would constitute an imminent hazard to the public health, he may bring suit in the district court for the district in which such laboratory is situated to enjoin continuation of such activity and, upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this section shall be granted without bond or by such court.

[(g)(1) Any party aggrieved by any final action taken under subsection (e) of this section may at any time within sixty days after the date of such action file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for judicial review of such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

[(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

[(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

[(4) The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by th Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

[(h) Any person who willfully violates any provision of this section or any rule or regulation promulgated thereunder shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine.

[(i) The provisions of this section shall not apply to any clinical laboratory operated by a licensed physician, osteopath, dentist, or podiatrist, or group thereof, who performs or perform laboratory tests or procedures, personally or through his or their employees, solely as an adjunct to the treatment of his or their own patients; nor shall such provisions apply to any laboratory with respect to tests or other procedures made by it for any person engaged in the business of insurance if made solely for purposes of determining whether to write an insurance contract or of determining eligibility or continued eligibility for payments thereunder.

[(j) In carrying out his functions under this section, the Secretary is authorized, pursuant to agreement, to utilize the services or facilities of any Federal or State or local public agency or nonprofit private agency or organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as he may determine.

[(k) Nothing in this section shall be construed as affecting the

power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with the provisions of this section or with the rules and regulations issued under this section.

[(l) Where a State has enacted or hereafter enacts laws relating to matters covered by this section, which provide for standards equal to or more stringent than the provisions of this section or than the rules and regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.]

* * * * * * *

[PART H—GRANTS TO ALASKA FOR MENTAL HEALTH

[PAYMENTS FOR CONSTRUCTION OF HOSPITAL FACILITIES

[SEC. 372. (a) There is authorized to be appropriated an amount not exceeding the total sum of $6,500,000, to remain available until expended, to enable the Surgeon General to make payments to Alaska as the total contribution of the Federal Government to be used in defraying the cost of construction of hospital and other facilities in Alaska needed for the carrying out of a comprehensive mental health program.

[(b) Such facilities shall be scheduled for construction in accordance with a comprehensive construction program, developed by Alaska in consultation with the Public Health Service and approved by the Surgeon General. Projects shall be constructed in accordance with such approved program and in accordance with plans and specifications for the project approved by the Surgeon General.

[(c) Upon certification by Alaska, based upon inspection by it, that work has been performed upon a project, or purchases have been made in accordance with approved plans and specifications, and that payment of an installment is due, the Surgeon General shall certify such installment for payment: *Provided however*, That the Surgeon General may cause the project to be inspected at any time, and if such inspection indicates that the project is not being constructed in accordance with approved plans and specifications, he may, after notice and affording opportunity for hearing, withhold further payment until he finds that adequate corrective measures have been taken.

[(d) The term "cost of construction" means the amount found necessary by the Surgeon General for the construction of a project and includes the construction and initial equipment of buildings (including medical transportation facilities), architects' and engineering fees, the cost of land acquired specifically for the purpose of the project, and on-site improvements.

[(e) If, within 20 years from the date of completion of construction, any hospital or other medical facility constructed with the aid of grants under this section shall cease to be a publicly owned facility operated for the care or treatment of patients under Alaska's mental health program, the United States shall be entitled to recover from Alaska the then value of the hospital or other medical facility, reduced, however, proportionately to the extent to which Alaska may have contributed to the cost of construction thereof.]

Part H—Clinical Laboratories

DEFINITIONS

Sec. 370. For purposes of this part—

(1)(A) Except as provided in subparagraph (B), the terms "laboratory" and "clinical laboratory" mean a facility (or any identifiable part of a facility)—

(A) for the biological, microbiological, serological, chemical, immunohematological, radioimmunological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, humans, or

(B) for the collection, processing, or transmission of such materials for such purposes.

(B) The terms "laboratory" or "clinical laboratory" do not include a facility (or identifiable part of a facility) exclusively engaged in (i) the collection, banking, processing, or transmission of human whole blood or its components or other tissues, (ii) transfusion services, (iii) plasmapheresis, (iv) compatibility testing, or (v) any combination of such activities.

(2) The term "interstate commerce" means (A) trade, traffic, commerce, transportation, transmission, or communication between any State and any place outside of such State, or (B) within the District of Columbia.

NATIONAL STANDARDS

Sec. 371. (a) Within two hundred and ten days of the date of the enactment of the Clinical Laboratory Improvement Act of 1978, the Secretary, after providing reasonable opportunity for consultation with representative public and private professional entities, shall publish proposed national standards for clinical laboratories. Within one year after such date of enactment, the Secretary shall promulgate such standards with such modifications as the Secretary deems appropriate, and such standards shall take effect upon their promulgation. Standards under this subsection may be amended by the Secretary.

(b)(1) National standards promulgated under subsection (a) for clinical laboratories shall be designed to assure consistent performance by clinical laboratories of accurate and reliable laboratory tests and other procedures and services (hereinafter in this part collectively referred to as "services") and shall—

(A) require clinical laboratories subject to the standards to maintain appropriate quality control programs,

(B) require such laboratories to maintain such records, equipment, and facilities as may be necessary for the proper and effective operation of such laboratories,

(C) require satisfactory performance by such laboratories on periodic proficiency tests developed in accordance with subsection (d),

(D) prescribe qualifications for directors and supervisory personnel of, and technologists employed in, such laboratories (which qualifications shall (i) not be limited solely to education requirements, (ii) include appropriate combinations of education, training, experience, and examination requirements, and (iii) be designed to insure the continued competence of such personnel),

(E) require supervisory personnel of such laboratories, through periodic practical examinations or by comparable methods, to evaluate, in accordance with guidelines prescribed by the Secretary, the proficiency of technicians employed in such laboratories,

(F) require such laboratories to provide assurances satisfactory to the Secretary that—

(i) directors, supervisory personnel, and technologists will meet applicable requirements prescribed under subparagraph (D), and

(ii) all technologists and technicians will, where appropriate, perform their duties under supervision and will perform only those duties for which they are qualified, as determined in accordance with subparagraphs (D) and (E), and

(G) include such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable services.

(2) For purposes of paragraph (1)—

(A) the term "technologist" means an individual employed in a laboratory who in performing services in such laboratory is required to excercise independent judgment, and

(B) the term "technician" means a person employed in a laboratory who is not required to exercise independent judgment in the technician's employment by the laboratory.

(c) The national standards promulgated under subsection (a) may vary on the basis of the type of services performed by such laboratories or the purposes for which such services are performed.

(d) Within one year of the date of the enactment of the Clinical Laboratory Improvement Act of 1978, the Secretary, in consultation with appropriate professional organizations, shall develop standards for proficiency testing of clinical laboratories subject to national standards in effect under this section, which proficiency testing standards (i) shall require such testing to be administered at least annually to all such laboratories; (ii) shall require a system of on-site testing of a laboratory's proficiency in the examination of specimens which system shall require such testing to be done in accordance with the procedures prescribed by paragraphs (1) and (2) of section 376(b); and (iii) may require a system for the testing of a laboratory's proficiency in the examination of specimens under which system the laboratory is not informed that its proficiency is being tested (commonly referred to as "blind proficiency testing").

APPLICATION OF NATIONAL STANDARDS

SEC. 372. (a) National standards for clinical laboratories in effect under section 371 shall be administered and enforced by the Secretary and shall, except as provided in subsections (b), (c), and (d)—

(1) apply to each clinical laboratory which is engaged in business in interstate commerce, and

(2) apply to any other clinical laboratory which is located in a State which (as determined under section 374) does not have primary enforcement responsibility for the regulation of clinical laboratories.

(b) The Secretary, upon request of a State which has primary enforcement responsibility for the regulation of clinical laboratories, shall authorize such State to regulate, under the standards of the State described in section 374 (a) (1), clinical laboratories which are located or doing at least 10 per centum of their business within the State and which are engaged in business in interstate commerce.

(c) (1) Except as provided in section 103(a) of the Clinical Laboratory Improvement Act of 1978, during the two-year period beginning on the date that national standards first take effect under section 371, such standards shall not apply to clinical laboratories which are not engaged in business in interstate commerce.

(2) During the two-year period beginning on the date that national standards for clinical laboratories first take effect under section 371 (or, in the case of a clinical laboratory which is not engaged in business in interstate commerce and which is not subject to section 103 (a) (2) of the Clinical Laboratory Improvement Act of 1978, during the two-year period beginning on the date such standards are first made applicable to such laboratory), the provisions of such standards prescribing qualifications for supervisory personnel or the provisions of such standards prescribing qualifications for technologists, or both such provisions, shall not apply to a clinical laboratory which—

(A) the Secretary determines is located in a rural area (as defined by the Secretary) in which there is not a sufficient number of individuals with the qualifications prescribed by such provisions for supervisory personnel or technologists, as the case may be,

(B) performs services solely for hospitals and licensed physicians, dentists, or podiatrists (or any combination of such practitioners) located within such a rural area, and

(C) provides the Secretary satisfactory assurances that it will take such actions as may be necessary to train individuals to meet such qualifications or to employ individuals with such qualifications.

(3) (A) The national standards for clinical laboratories shall not apply to any clinical laboratory—

(i) which is located in the office of a licensed physician, dentist, or podiatrist, or a group of such practitioners, and

(ii) in which the only services which are performed are services performed by such a practitioner in connection with the treatment of his patients.

(B) Except as provided under section 103(a)(2) of the Clinical Laboratory Improvement Act of 1978, the national standards for clinical laboratories shall not apply to any clinical laboratory—

(i) which is located in the office of, or supervised by, a licensed physician, dentist, or podiatrist, or a group of not more than five such practitioners,

(ii) in which the only services which are performed are services performed in connection with the treatment of the patients of such practitioner (or group of practitioners) or in connection with services provided for such patients by a physician assistant or nurse practitioner under the supervision of such practitioner or group, and

(iii) which is a participant in a proficiency testing program approved by the Secretary if such participation is required under section 103(b) of such Act.

(4) The Secretary shall, upon application, exempt, on such terms and conditions as may be appropriate, from the national standards for clinical laboratories any laboratory in which the only services which are performed are services for biomedical or behavioral research.

(5) Except as provided under section 104(b)(2) of the Clinical Laboratory Improvement Act of 1978, the national standards for clinical laboratories shall not apply to any highly specialized clinical laboratory engaged exclusively in the assessment of cardiac or pulmonary function.

(d)(1) Federal clinical laboratories under the jurisdiction of the Secretary shall be subject to national standards in effect under section 371 and any other Federal clinical laboratory in a State shall be subject to such standards unless (A) the laboratory is under the jurisdiction of any of the Armed Forces of the United States or the Administrator of Veterans' Affairs, or (B) the agency which has jurisdiction over such laboratory has in effect standards for such laboratory which are no less stringent than the national standards in effect under subsection (a).

(2) The Secretary shall bring the national standards in effect under section 371 to the attention of the Secretary of each military department and the Administrator of Veterans' Affairs so that such standards may be considered and applied as appropriate by such Secretaries and Administrator to clinical laboratories under their jurisdiction.

(e) Except as authorized under section 374, no State or political subdivision may adopt or continue in effect requirements (other than licensing requirements applicable to directors, supervisory personnel, technologists, or technicians in clinical laboratories and requirements applicable to clinical laboratories under a certificate of need program) which—

(A) are applicable to clinical laboratories, and

(B) are different from or in addition to the national standards for clinical laboratories in effect under section 371.

(f) Any clinical laboratory which is engaged in business in interstate commerce shall, during the period beginning on the date of the enactment of the Clinical Laboratory Improvement Act of 1978 and ending on the date such laboratory is required to have in effect a license issued under section 373, comply with the licensing requirements in effect under section 353 before such date of enactment.

LICENSES

SEC. 373. (a) The Secretary shall establish a system for the licensure of clinical laboratories subject to national standards in effect

under section 371. A license issued under such system for a clinical laboratory (1) shall specify the categories of services which such laboratory may perform, and (2) shall be valid for such period (but not in excess of thirty-six months) as the Secretary may prescribe. A fee may be required by the Secretary for the issuance or renewal of a license in an amount not to exceed $500. The Secretary may prescribe variances in such fees based on the volume of services performed by the clinical laboratories required to be licensed.

(b)(1) The system established under subsection (a) shall require the following as a condition to the issuance or renewal of a license under the system:

(A) The submission of an application in such form and manner as may be prescribed by the Secretary.

(B) A determination by the Secretary that the applicant meets the national standards in effect under section 371.

(C) The submission by the applicant to the Secretary and to the health systems agency serving the area in which the applicant is located of (i) an accurate itemized schedule of all current rates the applicant charges (including such a schedule of rates for common groupings of tests) for the laboratory services it provides, and (ii) such information as may be necessary to disclose any contractual relationships in effect between the applicant and physicians and other health professionals respecting the laboratory's services and the terms of any contracts between the applicant and such persons.

(2) From the information submitted in accordance with paragraph (1)(C) a health systems agency may not disclose—

(A) the identity of any person for whom an applicant for a license performed services, except that a health systems agency may make such a disclosure in response to a request of an officer or employee of the United States or a State made in accordance with regulations of the Secretary and in connection with the functions or duties of the officer or employee in the enforcement of this part or of a Federal or State criminal law; and

(B) any contractual relationship described in clause (ii) of such paragraph, except that, in accordance with regulations promulgated by the Secretary, the health systems agency may disclose (i) a contractual relationship between the applicant and any physician for the performance of services if the applicant receives compensation under title XVIII of the Social Security Act or under a State plan for medical assistance approved under title XIX of such Act for the performance of clinical laboratory services, and (ii) any contractual relationship described in such clause (ii) in response to a request of an officer or employee of the United States or a State made in connection with the functions or duties of the officer or employee in the enforcement of this part or a Federal or State criminal law.

(c)(1) If the Secretary finds, after reasonable notice and opportunity for hearing, that—

(A) a clinical laboratory licensed under this section is not in compliance with applicable national standards in effect under section 371, or

(*B*) *such laboratory has* (*i*) *failed to comply with reasonable requests of the Secretary for any information or specimens, or testing of specimens, the Secretary deem necessary to determine the laboratory's continued eligibility for its license under this section or continued compliance with applicable national standards in effect under section 371, or* (*ii*) *refused a request of the Secretary or any individual duly designated by him for permission to inspect, under section 376*(*b*), *the laboratory and its operations and pertinent records at any reasonable time,*

the Secretary may revoke such laboratory's license for the remainder of its term or may limit or suspend such laboratory's license until the laboratory has demonstrated to the satisfaction of the Secretary that the laboratory is in compliance with such national standards or such requests will be complied with, as the case may be.

(*2*) *If the Secretary finds, after reasonable notice and opportunity for a hearing, that a clinical laboratory licensed under this section—*

(*A*) *has been guilty of misrepresentation in obtaining the license;*

(*B*) *has engaged or attempted to engage in, or represented itself as entitled to perform, any laboratory service or category of services not authorized by the license;*

(*C*) *has engaged in a billing practice under which charges for laboratory services provided a patient, on whose behalf reimbursement* (*in whole or in part*) *for such charges is provided under a program receiving Federal financial assistance, are made at a higher rate than charges for comparable services provided a patient for whom such reimbursement is not made;*

(*D*) *has offered, paid, solicited, or received any* ~~*kickback or bribe in the form of money or any other thing of value*~~ **remuneration (including any kickback, bribe, finder's fee, or rebate, but excluding any discount or other reduction in price and excluding any amount paid by an employer for employment in the provision of the services) directly or indirectly, overtly or covertly, in cash or in kind** *in connection with the provision of clinical laboratory services; or*

(*E*) *has engaged in any false, fictitious, or fraudulent billing practice for the purposes of obtaining payment under any program the funds for which are provided in whole or in part by the United States,*

the Secretary may revoke such license for the remainder of its term or may make the laboratory or any person determined by the Secretary to have made the misrepresentation described in subparagraph (*A*) *or to have engaged in any activity described in subparagraph* (*B*),(*C*),(*D*), *or* (*E*) *ineligible to apply for a license under this section for such period* (*not to exceed two years*) *as the Secretary may prescribe, or take both such actions. A billing practice which results in different charges for the same laboratory services solely because of differences in administrative costs related to receiving reimbursement for the provision of such services shall not be considered a billing practice described in subparagraph* (*C*).

(*d*) *Any person who is convicted under subsection* (*a*) *of section 375 or under section 1877*(*b*) *or 1909*(*b*) *of the Social Security Act af-*

ter the date of enactment of the Clinical Laboratory Improvement Act of 1978 for a violation occurring after such date shall not be eligible to apply for a license under this section for a clinical laboratory during the ten-year period beginning on the date such person's conviction became final and the license of the laboratory involved in such violation shall be revoked.

(e) (1) Any person aggrieved by any final action taken under subsection (c) of this section may at any time within sixty days after the date of such action file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business for judicial review of such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon a hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, is supported by substantial evidence, shall be conclusive.

PRIMARY ENFORCEMENT RESPONSIBILITY

Sec. 374. (a) For purposes of this section, a State has primary enforcement responsibility for the regulation of clinical laboratories described in subsection (c) during any period for which the Secretary determines (pursuant to regulations prescribed under subsection (d)) that such State—

(1) has adopted (A) standards applicable to clinical laboratories which are no less stringent than the national standards in effect under section 371, and (B) a system for the licensure of laboratories which meets the requirements of subsection (b) and which includes provisions respecting applications and submissions to health systems agencies for the health service areas in which the applicants are located or doing at least 10 per centum of their business which provisions are no less stringent than the provisions of subsection (b) of section 373 and includes provisions respecting the suspension, revocation, and eligibility for licenses which provisions are no less stringent than the provisions of subsections (c) and (d) of such section;

(2) is able to enforce such State's standards, including enforcement by such monitoring and such inspections as the Secretary may require by regulation;

(3) will keep such records and make such reports with respect to its activities under paragraphs (1) and (2) as the Secretary may require by regulation;

(4) if it permits exemptions from the requirements of its standards which meet the requirements of paragraph (1)(A), permits such exemptions under conditions and in a manner which are no less stringent than the conditions and the manner in which exemptions are or may be granted under section 372(c);

(5) has adopted and can implement adequate procedures for the effective and timely control of health hazards which may result from an activity of a clinical laboratory within the State;

(6) has designated a single agency of the State to enforce its standards and to administer its system for licensure of clinical laboratories; and

(7) for the purpose of avoiding the application of duplicative requirements to clinical laboratories, will coordinate with other States in carrying out its primary enforcement responsibilities.

(b) For the purpose of primary enforcement responsibility under this section, a State system for the licensure of clinical laboratories—

(1) shall prescribe that licenses issued under such system shall be valid for such period (but not in excess of thirty-six months) as is prescribed under the system, and may require a fee for the issuance or renewal of a license in an amount (not in excess of $500) determined under the system;

(2) may provide for variances in such fees based on volume of services performed by the clinical laboratories required to be licensed; and

(3) shall provide that licenses issued for a clinical laboratory shall specify the categories of services which such laboratory may perform.

(c) The clinical laboratories subject to regulation by a State which has primary enforcement responsibility are—

(1) clinical laboratories (other than clinical laboratories described in section 372(d)) which are located within such State and which are not engaged in business in intertate commerce, and

(2) if authorized under section 372(b), any other clinical laboratory (other than a clinical laboratory described in section 372(d)) engaged in business in interstate commerce and located or doing at least 10 per centum of its business within the State.

(d)(1) The Secretary shall, by regulation (proposed within one year of the date of the enactment of the Clinical Laboratory Improvement Act of 1978), prescribe the manner in which a State may apply to the Secretary for a determination that the State has met the requirements of subsection (a), the manner in which and the standards upon which the determination will be made, the period for which the determination will be effective, and the manner in which the Secretary may determine that such requirements are no longer met. The Secretary shall, at least every two years, review the clinical laboratory regulatory activities of a State with primary enforcement responsibility

to determine if the State continues to meet the requirements of subsection (a).

(2) Regulations under paragraph (1) shall require that before a determination of the Secretary that a State has not met the requirements of subsection (a) or no longer meets such requirements may become effective, the Secretary shall notify such State of the determination and the reasons therefor, shall provide an opportunity for public hearings on the determination, and, in the case of a determination that such requirements are no longer being met by a State, shall prescribe the period within which such State must comply with such requirements to retain its primary enforcement responsibility.

(3) Regulations under paragraph (1) shall be promulgated (with such modifications as the Secretary deems appropriate) within ninety days of the publication of the proposed regulations in the Federal Register. The Secretary shall promptly notify in writing the chief executive officer of each State of the promulgation of regulations under paragraph (1). Such notice shall contain a copy of the regulations and shall specify a State's authority under this part when it is determined to have primary enforcement responsibility for clinical laboratories.

(e) When an application is submitted in accordance with the Secretary's regulations under subsection (d), the Secretary shall within ninety days of the date on which such application is submitted (1) make the determination applied for, or (2) deny the application and notify the applicant in writing of the reasons for the denial.

PROHIBITED ACTS

SEC. 375. (a) Any person who solicits, or accepts, directly or indirectly, any specimen for a laboratory service by a clinical laboratory which is required to have in effect a license issued by the Secretary under section 373 and which does not have such a license in effect or which is not authorized by its license to perform such service, shall be fined not more than $10,000 or imprisoned for not more than one year, or both.

(b) No clinical laboratory which is required to have in effect a license issued by the Secretary under section 373 or a license issued by a State with primary enforcement responsibility for the regulation of clinical laboratories and which does not have such a license in effect may—

(1) receive a grant, contract, or other form of financial assistance under this Act, or

(2) charge or collect for laboratory services for any entity which receives a grant, contract, or other form of financial assistance under this Act.

The charges of such a laboratory may not be included in determining Federal payments under title XVIII or XIX of the Social Security Act.

ENFORCEMENT

SEC. 376. (a) Whenever the Secretary has reason to believe that continuation of any activity by a clinical laboratory required to be licensed under section 373 by the Secretary would constitute a significant hazard to the public health, he may bring suit in the United

States district court for the district in which such laboratory is situated to enjoin continuation of such activity and, upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order by the court shall be granted without bond.

(b)(1) For purposes of enforcement of this part, individuals designated as inspectors by the Secretary, upon presenting appropriate credentials and a written notice to the person in charge of the clinical laboratory to be inspected and after clearly informing him of their authority, are authorized to enter and inspect any laboratory in a State which is subject to national standards in effect under section 371. A separate notice shall be given for each such inspection, but a separate notice shall not be required for each entry made during the period covered by the inspection. Such an inspection (A) shall be made during the normal business hours of the laboratory being inspected and in a reasonable manner, and (B) may extend only to relevant equipment, materials, containers, records files, papers (including financial data, sales data, and pricing data), processes, controls, facilities, and all other things in the laboratory bearing on whether it is being operated in compliance with such standards.

(2) Upon completion of any such inspection and prior to leaving the premises inspected, the inspector shall give to the person in charge a preliminary report which summarizes any conditons or practices observed by the inspector which, in his judgment, indicate a violation of national standards in effect under section 371. The inspector shall also prepare a written final report of his findings and send it to such person within thirty days of the completion of the inspection.

(3) No individual designated by the Secretary to enter a laboratory and conduct an inspection pursuant to paragraph (1) shall be required to obtain a search warrant from any judicial officer prior to entering any laboratory and conducting any inspection which is authorized by such paragraph.

(4) For the purpose of carrying out the review prescribed by section 374(d)(1) (relating to primary enforcement responsibility), the Secretary may designate individuals to conduct inspections of clinical laboratories which are not subject to national standards in effect under section 371 to determine if such laboratories are in compliance with applicable State standards. Each such inspection shall be conducted in accordance with the requirements of paragraph (1).

(c)(1) No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation or the terms, conditions, or privileges of his employment because the employee (or any person acting pursuant to a request of the employee)—

(A) caused to be commenced a proceeding under section 373(c) or 375(a) or subsection (a) of this section, a proceeding by a State in carrying out its primary enforcement responsibility, or an inspection under subsection (a) or by such a State in carrying out such responsibility;

(B) testified or is about to testify in any such proceeding; or

(C) assisted or participated or is about to assist or participate in any manner in such a proceeding, inspection, or in any other action to carry out the purposes of this part.

(2) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of paragraph (1) may, within thirty days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this subsection referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(3) Upon receipt of a complaint filed under paragraph (2), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within thirty days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by paragraph (4) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(4) If in response to a complaint filed under paragraph (2) the Secretary determines that a violation of paragraph (1) has occurred, the Secretary shall order (A) the person who committed such violation to take affirmative action to abate the violation, (B) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, and (C) the award of compensatory damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(5)(A) Any person adversely affected or aggrieved by an order issued under paragraph (4) may obtain review of the order in the United States court of appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(B) An order of the Secretary, with respect to which review could have been obtained under subparagraph (A), shall not be subject to judicial review in any criminal or other civil proceeding.

(6) Whenever a person has failed to comply with an order issued under paragraph (4), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this paragraph, the district courts of the United States shall have juris-

diction to grant all appropriate relief, including injunctive relief and compensatory damages. Civil actions brought under this paragraph shall be heard and decided expeditiously.

(7) Any nondiscretionary duty imposed by this subsection is enforceable in mandamus proceeding brought under section 1361 of title 28, United States Code.

(8) Paragraph (1) shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this part or of a clinical laboratory regulatory requirement of a State with primary enforcement responsibility.

AGREEMENTS AND ASSISTANCE

SEC. 377. (a) The Secretary and any State which has primary enforcement responsibility for the regulation of clinical laboratories may enter into agreements with qualified public or nonprofit private entities which, as determined by the Secretary or such State, as the case may be, have adopted laboratory standards at least as stringent as those in effect under section 371 (or in the case of agreements to be entered into by such a State, at least as stringent as those in effect in such State under section 374) under which agreements such entities would—

(1) make such inspections as the Secretary or such State may require to determine if clinical laboratories are in compliance with applicable standards,

(2) administer (A) such proficiency tests as the Secretary or such States may require for clinical laboratories, or (B) such examinations of laboratory personnel as the Secretary or such State may require, or

(3) do any combination of the activities described in paragraphs (1) and (2).

An agreement entered into under this subsection with an entity may provide for financial assistance to the entity to assist it in meeting its costs of conducting the activities prescribed for it by the agreement.

(b) If the Secretary has entered into an agreement under the first sentence of section 1864(a) of the Social Security Act for the enforcement of the requirements of section 1861 of such Act with respect to clinical laboratories by a State which does not have primary enforcement responsibility for the regulation of clinical laboratories, the Secretary may enter into an agreement under this subsection with such a State for the enforcement within such State of the requirements of national standards in effect under section 371 with respect to clinical laboratories not subject to the requirements of such section 1861. An agreement entered into under this subsection with a State may provide for financial assistance to the State to assist it in meeting its costs of enforcing the requirements of the national standards.

(c)(1) The Secretary may enter into agreements with States with primary enforcement responsibility under which agreements financial assistance will be provided to such States to assist them in meeting the cost of administering and enforcing their programs for the regulation of clinical laboratories which are not covered under agreements authorized by title XVIII of the Social Security Act.

(2) The Secretary may provide technical assistance to any State to assist it in meeting the requirements of section 374.

(d) For the purpose of agreements authorized by subsections (a), (b), and (c), there are authorized to be appropriated $3,000,000 for the fiscal year ending September 30, 1979, $3,000,000 for the fiscal year ending September 30, 1980, and $3,000,000 for the fiscal year ending September 30, 1981.

ANNUAL REPORT

SEC. 378. (a) Not later than the first January 1 which occurs more than 9 months after national standards first take effect under section 371 and each succeeding January 1, the Secretary shall make a report to the Congress (1) respecting the accuracy and reliability of services performed by clinical laboratories during the preceding fiscal year, and (2) evaluating the effect of the costs of clinical laboratory services on the overall cost of health care services and the relation of the costs of such tests and procedures to the costs of the health care services for which the services are conducted.

* * * * * * *

SOCIAL SECURITY ACT

TITLE XI—GENERAL PROVISIONS AND PROFESSIONAL STANDARDS REVIEW

* * * * * * *

PART A—GENERAL PROVISIONS

* * * * * * *

DISCLOSURE OF OWNERSHIP AND RELATED INFORMATION

SEC. 1124. (a)(1) The Secretary shall by regulation or by contract provision provide that each disclosing entity (as defined in paragraph (2)) shall—

(A) as a condition of the disclosing entity's participation in, or certification or recertification under, any of the programs established by titles V, XVIII, XIX, and XX, or

(B) as a condition for the approval or renewal of a contract or agreement between the disclosing entity and the Secretary or the appropriate State agency under any of the programs established under titles V, XVIII, XIX, and XX,

supply the Secretary or the appropriate State agency with full and complete information as to the identity of each person with an ownership or control interest (as defined in paragraph (3)) in the entity or in any subcontractor (as defined by the Secretary in regulations) in which the entity directly or indirectly has a 5 per centum or more ownership interest, *and in the case of a disclosing entity which is an independent clinical laboratory, ~~permit the Secretary to examine its records to determine whether a physician has billed any individual, has billed as~~*

~~*provided under section 1842(b)(3)(B)(ii), or has billed a State plan for medical assistance approved under title XIX for diagnostic laboratory services performed by such laboratory and the amount charged for such services*~~ **furnish such information and access to its records as the Secretary may require to determine whether and in what amounts the laboratory has charged a physician for laboratory services performed by the laboratory.**

PERCENTAGE ARRANGEMENTS OF HOSPITAL-BASED PHYSICIANS

Sec. 1127. (a) Notwithstanding any other provision of this Act, if a physician (or physicians) performs a professional service in a hospital and the hospital's payment to the physician (or physicians) for the service is based on a percentage of the hospital's charges (or of hospital amounts otherwise calculated) for the service, no part of such payment shall be considered reasonable for the purpose of reimbursement under title V, XVIII, or XIX, to the extent that the part exceeds the sum of—

(1) the compensation which would reasonably have been paid by the hospital to the physician (or physicians) performing the service (taking into consideration the local and individual circumstances under which the services are provided in that hospital) and additional costs that would have been incurred by the hospital, if the service had been performed by the physician (or physicians) in an employment relationship with the hospital, and

(2) the cost of such other reasonable expenses (including a reasonable allowance for traveltime and other reasonable types of expense related to differences in acceptable methods of organizing the provision of the service) incurred by the physician (or physicians) in performing the service, as the Secretary determines to be appropriate.

(b) Notwithstanding any other provision of this Act, if a physician (or physicians) furnishes professional services in a hospital to patients of the hospital and if these services are furnished in the hospital under a rental or lease arrangement under which arrangement the hospital is paid an amount that is based (directly or indirectly) on a percentage, fraction, or proportion of the charges made for the services furnished, the amount that shall be treated as a reduction from the hospital's costs otherwise allowable under titles V, XVIII, and XIX, with respect to its receipt of payments under the arrangement, shall be the greater of—

(1) the amount paid to the hospital under the arrangement with respect to the services furnished, or

(2) the amount by which (A) the charges made by the physician (or physicians) for the furnishing of the services, exceeds (B) the amount of the costs which would have been incurred for the furnishing of the services if they were furnished directly by the hospital through individuals who were all employed on a reasonable compensation basis by the hospital, rather than under such arrangement.

* * * * * * *

PROCEDURES FOR DETERMINING REASONABLE COST AND CHARGES FOR LABORATORY SERVICES

~~SEC. 1132. In determining the amount of any payment for a clinical laboratory service (other than such a service which is provided by a clinical laboratory which is located in a hospital and which provides service primarily in connection with the furnishing by the hospital of other inpatient or outpatient services) furnished under title XVIII, under a program established pursuant to title V, or under a State plan for medical assistance approved under title XIX, no reimbursement will be available for any element of the cost or charge for such service to the extent that such element is—~~

~~(1) a commission (other than a commission paid to an employee of a clinical laboratory in the course of its usual and customary business) or finder's fee, or~~

~~(2) an amount payable for any facility (or part or activity thereof) under any rental or lease arrangement, where such amount (A) is unrelated or disproportionate to the market value of the facility (or part thereof), or (B) is, directly or indirectly, determined, wholly or in part, as a per centum, fraction, or portion of the charge or cost attributed to the laboratory service.~~

* * * * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * * * *

PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

DESCRIPTION OF PROGRAM

* * * * * * *

CONDITIONS OF AND LIMITATIONS ON PAYMENT FOR SERVICES

Requirement of Requests and Certifications

SEC. 1814. (a) Except as provided in subsections (d) and (g) and in section 1876, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1866 and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year;

(2) physician certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that—

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of inpatient tuberculosis hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the treatment of an individual for tuberculosis; and such treatment can or could reasonably be expected to (i) improve the condition for which such treatment is or was necessary or (ii) render the condition noncommunicable;

(C) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and [9] (*10*) of section 1861 (e)) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(D) in the case of post-hospital home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1861(m)(7)) and needed skilled nursing care on an intermittent basis, or physical or speech therapy, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and [9] (*10*) of section 1861(e)) or post-hospital extended care services; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; and such services are or were furnished while the individual was under the care of a physician; or

(E) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status, requires hospitalization in connection with the provision of such dental services;

* * * * * * *

SCOPE OF BENEFITS

SEC. 1832. (a) The benefits provided to an individual by the insurance program established by this part shall consist of—

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2); and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for—

* * * * * * *

(C) outpatient physical therapy services, other than services to which the (next to last) **second** sentence of section 1861(p) applies; and

(D) rural health clinic services.

(b) For definitions of "spell of illness", "medical and other health services", and other terms used in this part, see section 1861.

PAYMENT OF BENEFITS

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to expenses incurred for radiological or pathological services for which payment may be made under this part, furnished to an inpatient of a hospital by a physician in the field of radiology or pathology, the amounts paid shall be equal to 100 percent of the reasonable charges for such services, (C) with respect to expenses incurred for those physicians' services for which payment may be made un-

der this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, and (D) with respect to diagnostic tests performed in a laboratory for which payment is made under this part to the laboratory, the amounts paid shall be equal to 100 percent of the negotiated rate for such tests (as determined pursuant to subsection ((g)) **(h)** of this section),

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraph (D) of section 1832(a)(2))—with respect to home health services, 100 percent, and with respect to other services, 80 percent of—

(A) the lesser of (i) the reasonable cost of such services, as determined under section 1861(v), or (ii) the customary charges with respect to such services; or

(B) if such services are furnished by a public provider of services free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2); or

(C) if such services are services to which the (next to last) **second** sentence of section 1861(p) applies, the reasonable charges for such services; and

* * * * * * *

(g) In the case of services described in the (next to last) **second** sentence of section 1861(p), with respect to expenses incurred in any calendar year, no more than $100 shall be considered as incurred expenses for purposes of subsections (a) and (b).

((g)) (h) With respect to diagnostic tests performed in a laboratory for which payment is made under this part to the laboratory, the Secretary is authorized to establish a payment rate which is acceptable to the laboratory and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such a rate.

* * * * * * *

ENROLLMENT PERIODS

SEC. 1837. (a) * * *

* * * * * * *

(g) All of the provisions of this section shall apply to individuals satisfying subsection (f), except that—

(1) in the case of an individual who satisfies subsection (f) by reason of entitlement to disability insurance benefits described in section (226(a)(2)(B)) **226(b)**, his initial enrollment period shall begin on the first day of the later of (A) April 1973 or (B) the third month before the 25th consecutive month of such entitlement, and shall reoccur with each continuous period of eligibility (as defined in section (1839(e)) **1839(f)**) and upon attainment of age 65;

* * * * * * *

PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * * * *

USE OF CARRIERS FOR ADMINISTRATION OF BENEFITS

SEC. 1842. (a) * * *

* * * * * * *

~~(h) If a physician's bill or request for payment on behalf of a physician includes a charge to a patient for laboratory services, the payment for such charge shall be determined as follows:~~

~~(1) If the bill or request for payment indicates that the physician who submitted such bill or for whom the request for payment was submitted personally performed or supervised the performance of such services or that another physician with whom that physician shares his practice personally performed or supervised such services, the payment shall be the reasonable charge for such services.~~

~~(2) If the bill or request for payment indicates that such services were performed by a laboratory, identifies such laboratory, and indicates the amount the laboratory billed the physician who submitted such bill or for whom the request for payment was made, payment for such services shall be the lower of—~~

~~(A) the reasonable charge for such services by such laboratory, or~~

~~(B) the amount so billed by the laboratory plus a nominal fee to cover the physician's cost in collecting and handling the sample on which such services were performed.~~

~~(3) If the bill or request for payment (A) does not indicate who performed such services, or (B) indicates that such services were performed by a laboratory but does not identify the laboratory or include the amount charged by the laboratory, payment shall be the lowest charge at which the carrier estimates such services could have been secured by a physician from a laboratory in the applicable locality.~~

(h) If a physician's bill or request for payment for a physician's services includes a charge to a patient for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows:

(1) If the bill or request for payment indicates that the physician who submitted the bill or for whose services the request for payment was made personally performed or supervised the performance of the test or that another physician with whom that physician shares his practice personally performed or supervised the test, the payment shall be the reasonable charge for the test (less the applicable deductible and coinsurance amounts).

(2) If the bill or request for payment indicates that the test was performed by a laboratory, identifies the laboratory, and indicates the amount the laboratory charged the physician who submitted the bill or for whose services the request for payment was made, payment for the test shall be the lower of—

(A) the laboratory's reasonable charge to individuals enrolled under this part for the test, or

(B) the amount the laboratory charged the physician for the test,

plus a nominal fee (where the physician bills for such a service) to cover the physician's costs in collecting and handling the sample on which the test was performed (less the applicable deductible and coinsurance amounts).

(3) If the bill or request for payment (A) does not indicate who performed the test, or (B) indicates that the test was performed by a laboratory but does not identify the laboratory or include the amount charged by the laboratory, payment shall be the lowest charge at which the carrier estimates the test could have been secured by a physician from a laboratory serving the locality (less the applicable deductible and coinsurance amounts).

* * * * * * *

PART C—MISCELLANEOUS PROVISIONS

DEFINITION OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

Spell of Illness

(a) * * *

* * * * * * *

Hospital

(e) The term "hospital" (except for purposes of sections 1814(d), 1814(f) and 1835(b), subsection (a)(2) of this section, paragraph (7) of this subsection, and subsections (i) and (n) of this section) means an institution which—

(1) * * *

* * * * * * *

(8) has in effect an overall plan and budget that meets the requirements of subsection (z) : [and]

(9) meets applicable Federal or State licensing requirements under part H of title III of the Public Health Service Act with respect to any laboratory ~~(as defined in subsection (a)(1) of such part H of title III)~~ which is a part of the institution; and

[9] *(10)* meets such other requirements as the Secretary finds necessary in the interest of the health and safety of the individuals are furnished services in the institution.

For purposes of subsection (a)(2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. For purposes of sections 1814(d) and 1835(b) (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections), section 1814(f)(2), and subsections (i) and (n) of this section, such term includes any institu-

tion which (i) meets the requirements of paragraphs (5) and (7) of this subsection, (ii) is not primarily engaged in providing the services described in section 1861(j)(1)(A) and (iii) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of section 1861(r) to inpatients diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. For purposes of section 1814(f)(1), such term, includes an institution which (i) is a hospital for purposes of sections 1814(d), 1814(f)(2), and 1835(b) and (ii) is accredited by the Joint Commission on Accreditation of Hospitals, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program be essentially equivalent to those of the Joint Commission on Accreditation of Hospitals. Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a)(2), include any institution which is primarily for the care and treatment of mental diseases or tuberculosis unless it is a tuberculosis hospital (as defined in subsection (g)) or unless it is a psychiatric hospital (as defined in subsection (f)). The term "hospital" also includes a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts, but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1865.

Psychiatric Hospital

(f) The term "psychiatric hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through [9] (*10*) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A;

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution; and

(5) is accredited by the Joint Commission on Accreditation of Hospitals.

In the case of an institution which satisfies paragraphs (1) and (2) of the proceeding sentence and which contains a distinct part which

also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a "psychiatric hospital" if the institution is accredited by the Joint Commission on Accreditation of Hospitals or if such distinct part meets requirements equivalent to such accreditation requirements as determined by the Secretary.

Tuberculosis Hospital

(g) The term "tuberculosis hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, medical services for the diagnosis and treatment of tuberculosis;

(2) satisfies the requirements of paragraphs (3) through [(9)] (*10*) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals covered by the insurance program established by part A;

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution; and

(5) is accredited by the Joint Commission on Accreditation of Hospitals.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a "tuberculosis hospital" if the institution is accredited by the Joint Commission on Accreditation of Hospitals or if such distinct part meets requirements equivalent to such accreditation requirements as determined by the Secretary.

* * * * * * *

Skilled Nursing Facility

(j) The term "skilled nursing facility" means (except for purposes of subsection (a)(2)) an institution (or a distinct part of an institution) which has in effect a transfer agreement (meeting the requirements in subsection (1)) with one or more hospitals having agreements in effect under section 1866 and which—

(1) * * *

* * * * * * *

(15) meets such other conditions relating to the health and safety of individuals who are furnished services in such institution or relating to the physical facilities thereof (*including applicable Federal or State licensing requirements under part H of title III of the Public Health Service Act with respect to any laboratory which is a part of the institution*) as the Secretary may find necessary (subject to the second sentence of section 1863), except that the Secretary shall not require as a condition of participation that medical social services be furnished in any such institution. Notwithstanding any other provision of law, all in-

formation concerning skilled nursing facilities required by this subsection to be filed with the Secretary shall be made available to Federal or State employees for purposes consistent with the effective administration of programs established under titles XVIII and XIX of this of this Act;

* * * * * * *

Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2) (A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services; and

(3) diagnostic X-ray tests (including tests under the supervi-

(E) rural health clinic services;

sion of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for a reduction of fractures and disclocations;

(6) durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condidition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e) (1) or (j) (1) of this section), whether furnished on a rental basis or purchased;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care) including replacement of such devices; and

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition.

[No diagnostic tests performed in any laboratory which is independent of a physician's office, a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1814(d)) shall be included within paragraph (3) unless such laboratory—

[(10) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

[(11) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.]

No diagnostic ~~test~~ **tests** *performed in any laboratory shall be included in paragraph (3) unless such laboratory meets applicable Federal or State licensing requirements under part H of title III of the Public Health Service Act,* **or, if those requirements are not applicable, meets such conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.** There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which—

[12](*10*) would not be included under subsection (b) if it were furnished to an inpatient of a hospital; or

[13](*11*) is furnished under arrangements referred to in such paragraph (2)(C) unless furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

None of the itme and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) shall be included unless such other conditions are met as the Secretary may find necesary relating to health and safety of individuals with respect to whom such items and services are furnished.

* * * * * * *

USE OF STATE AGENCIES TO DETERMINE COMPLIANCE BY PROVIDERS OF SERVICES WITH CONDITIONS OF PARTICIPATION

SEC. 1864. (a) The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of deter-

mining whether an institution therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether a facility there is in a rural health clinic as defined in section 1861(a)(2), or whether a laboratory meets the requirements of [paragraphs (10) and (11) of section 1861(s)] *section 1861(e)(9)* ~~*and*~~, **section 1861(j)(15), or** *the second sentence of section 1861(s)*, or whether a clinic, rehabilitation agency or public health agency meets the requirements of subparagraph (A) or (B), as the case may be, of section 1861(p)(4)*; except that the Secretary may not make an agreement with a State under this sentence for the purpose of determining whether a laboratory meets* ~~*the requirements of the second sentence of section 1861(s) or*~~ *the requirements of section 1861(e)(9)*, **section 1861(j)(15), or the second sentence of section 1861(s)** (*or include provision for such purpose in any such agreement*) *unless either* ~~*such*~~ **the** *State has primary enforcement responsibility for the regulation of clinical laboratories, as determined under part H of title III of the Public Health Service Act, or the State provides assurances satisfactory to the Secretary that it will implement procedures for the enforcement of such requirements.* To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, rural health clinic or home health agency (as those terms are defined in section 1861) may be treated as such by the Secretary. Any State agency which has such an agreement may (subject to approval of the Secretary) furnish to a skilled nursing facility after proper request by such facility, such specialized consultative services (which such agency is able and willing to furnish in a manner satisfactory to the Secretary) as such facility may need to meet one or more of the conditions specified in section 1861(j). Any such services furnished by a State agency shall be deemed to have been furnished pursuant to such agreement. Within 90 days following the completion of each survey of any health care facility, rural health clinic, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place the pertinent findings of each such survey relating to the compliance of each such health care facility, rural health clinic, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this title and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such health care facility, rural health clinic, laboratory, clinic, agency, or organization.

* * * * * * *

EFFECT OF ACCREDITATION

SEC. 1865. (a) Except as provided in subsection (b) and the second sentence of section 1863, if—

(1) an institution is accredited as a hospital by the Joint Commission on Accreditation of Hospitals, and

(2) such institution (if it is included within a survey described in section 1864(c)) authorizes the Commission to release to the Secretary (on a confidential basis) upon his request (or such

State agency as the Secretary may designate) a copy of the most current accreditation survey of such institution made by such Commission,

then, such institution shall be deemed to meet the requirements of the numbered paragraphs of section 1861(e); except—

(3) paragraph (6) thereof, [and]

(4) paragraph (9) thereof, and

[(4)](*5*) any standard, promulgated by the Secretary pursuant to paragraph [9](*10*) thereof, which is higher than the requirements prescribed for accreditation by such Commission.

If such Commission, as a condition for accreditation of a hospital, requires a utilization review plan (or imposes another requirement which serves substantially the same purpose), *imposes standards with respect to laboratories which the Secretary (and the applicable State agency designated in accordance with Section 374(a)(6) of the Public Health Service Act, in the case of any laboratory in a State which has primary enforcement responsibility under part H of title III of such Act) determines are at least equivalent to the national standards for clinical laboratories in effect under section 371 of such Act*, or imposes a standard which the Secretary determines is at least equivalent to the standard promulgated by the Secretary as described in paragraph [(4)](*5*) of this subsection, the Secretary is authorized to find that all institutions so accredited by such Commission comply also with section 1861(e)(6), *section 1861(e)(9)*, or the standard described in such paragraph [(4)](*5*), as the case may be. In addition, if the Secretary *(and the applicable State agency designated in accordance with Section 374(a)(6) of the Public Health Service Act, to the extent that licensing requirements for laboratories under part H of title III of such Act, as specified in section 1861(e)(9) or 1861(j)(15) of this Act, are involved, if the institution or agency is located in a State which has primary enforcement responsibility under part H of title III of such Act)* finds that accreditation of an institution or agency by the American Osteopathic Association or any other national accreditation body provides reasonable assurance that any or all of the conditions of section 1861 (e), (j), or (o), as the case may be, are met, he may, to the extent he deems it appropriate, treat such institution or agency as meeting the condition or conditions with respect to which he made such finding.

* * * * * * *

AGREEMENTS WITH PROVIDERS OF SERVICES

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

* * * * * * *

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made under this title because payment for expenses incurred for such items or services may not be made by reason of

the provisions of paragraph (1) or (9) of section 1862(a), but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary's determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title, and

* * * * * * *

OVERPAYMENTS ON BEHALF OF INDIVIDUALS AND SETTLEMENT OF CLAIMS FOR BENEFITS ON BEHALF OF DECEASED INDIVIDUALS

SEC. 1870. (a) * * *

* * * * * * *

(c) There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII or would be against equity and good conscience. Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) of section 1862(a) and (B) if the Secretary's determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

* * * * * * *

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

* * * * * * *

STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) * * *

* * * * * * *

(23) except in the case of Puerto Rico, the Virgin Islands, and Guam, provides that any individual eligible for medical assistance (including drugs) may obtain such assistance for any institution, agency, community pharmacy, or person, qualified to

perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services; and a State plan shall not be deemed to be out of compliance with the requirements of this paragraph or paragraph (1) or (10) solely by reason of the fact that the State (or any political subdivision thereof) (*A*) has entered into a contract with an organization which has agreed to provide care and services in addition to those offered under the State plan to individuals eligible for medical assistance who reside in the geographic area served by such organization and who elect to obtain such care and services from such organization, or by reason of the fact that the plan provides for payment for rural health clinic services only if those services are provided by a rural health clinic, *or* (*B*) *during the three-year period beginning on the date of enactment of the Clinical Laboratory Improvement Act of 1978, has made arrangements through a competitive bidding process or otherwise for the purchase of laboratory services referred to in section 1905 (a) (3), if the Secretary has found that (i) adequate services will be available under such arrangements, (ii) such laboratory services will be provided only through laboratories (I) which meet the requirements of section 1861(e) (9), paragraphs (10) and (11) of section 1861(s), or part H of title III of the Public Health Service Act, and such additional requirements as the Secretary may require, and (II) no more than 75 per centum of whose charges for such services are for services provided to individuals who are entitled to benefits under this title or under part A or part B of title XVIII, and (iii) charges for services provided under such arrangements are made at the lowest rate charged (determined without regard to administrative costs costs which are related solely to the method of reimbursement for such services) for comparable services by the provider of such services, or, if charged for on a unit price basis, such charges result in aggregate expenditures not in exces of expenditures that would be made if charges were at the lowest rate charged for comparable services by the provider of such services*;

* * * * * * *

(28) provide that any skilled nursing facility receiving payments under such plan must satisfy all of the requirements contained in section 1861(j), except that the exclusion contained therein with respect to institutions which are primarily for the care and treatment of mental diseases and tuberculosis shall not apply for purposes of this title , *and provide that any laboratory services paid for under such plan must be provided by a laboratory which during the three-year period beginning on the date of enactment of the Clinical Laboratory Improvement Act of 1978 meets the requirements of section 1861(e) (9) or paragraphs (10) and (11) of section 1861(s) and after the expiration of such period is licensed in accordance with part H of title III of the Public Health Service Act;*

* * * * * * *

(30) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy, and quality of care *and, in the case of laboratory services referred to in section 1905(a)(3), such payments do not exceed the lowest amount charged (determined without regard to administrative costs which are related solely to the method of reimbursement for such services) to any person or entity for such services by that provider of laboratory services;*

* * * * * * *

(39) provide that, subject to subsection (g), whenever the single State agency which administers or supervises the administration of the State plan is notified by the Secretary under section 1862(e)(2)(A) that a physician or other individual practitioner has been suspended from participation in the program under title XVIII, the agency shall promptly suspend such physician or practitioner from participation in the plan for not less than the period specified in such notice, and no payment may be made under the plan with respect to any item or service furnished by such physician or practitioner during the period of the suspension under this title; [and]

(40) require each health services facility or organization which receives payments under the plan and of a type for which a uniform reporting system has been established under section 1121(a) to make reports to the Secretary of information described in such section in accordance with the uniform reporting system (established under such section) for that type of facility or organization [*; and*]

(41) if the State plan makes provision for payment to a physician for laboratory services the performance of which such physician (or any other physician with whom he shares his practice) did not personally perform or supervise, include provision to insure that payment under the State plan for such laboratory services not exceed the payment authorized for such services by section 1842(h).

* * * * * * *

○